DECEMBER 2020 # 93

the Analytical Scientist®

The Innovation Awards 2020

The Innovation Awards are back, but which developments are leading the pack in 2020?

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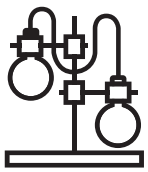

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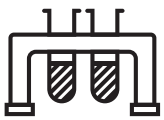

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Full Steam Ahead!

"We will soon be arriving at Innovation Station" – celebrating scientific success in stormy weather

If we could hand each of our readers an award for hard work and perseverance in 2020, we would. It's been a difficult year (to say the least), and it feels appropriate that we end it as we always do – by celebrating innovation.

We've all had to innovate amidst the pandemic – from changing how we meet with family and friends to finding unique ways of continuing essential work from a safe distance. Not content to chug along, the analytical science engine roars towards better, faster, stronger, smarter, simpler – whatever the weather (no snow or "leaves on the line" here).

Our Innovation Awards (page 14) provide some great examples of this full-steam-ahead approach. As always, nominations were submitted by you, our readers, and ranked by our esteemed (and anonymous) judges. The result: 15 runaway solutions that are set to transform our laboratories – and our ways of working. (Without giving too much away, we explore tales of endurance from one of the winners in our second feature on page 34. Why only tell half the story, right?)

Though some aspects of our world continued apace, let's not forget the emergency brake applied to the 2020 conference and events calendar – a serious blow for the many close communities within the sphere of analytical science. With some shows canceled and others made totally digital, adaptation (and yet more innovation) has been the name of the game. Yet, questions remain as to whether these virtual meetings – and their counterpart tools for delivering lectures to students – match their physical counterparts (as explored on page 10).

But there does seem to be light at the end of the tunnel! The last few weeks have brought news of promising vaccines – a flicker of hope as we near the end of a particularly gloomy journey. Again, analytical scientists are at the very heart of ensuring the absolute safety of the billions of doses needed for an entire planet (see more on page 42).

A change of tracks is certainly on the horizon, but that's not to say our destination is assured. Many platforms remain unexplored and dark corners stay unilluminated. Continued dedication in the coming months will be crucial in supporting future endeavors – and our much-anticipated arrival into Normality Station.

Right now, that glorious return feels tangibly (or perhaps tormentingly) close. In the meantime, I hope you all have a chance to blow off some steam over the coming holiday season; even those of you on the frontline of science need time in the engine shed.

Matthew Hallam
Editor

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We usher in the return of our annual Innovation Awards. See who made the cut on page 14

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Upfront

Research
Innovation
Trends

Water on Sunlit Moon

A unique spectral signature confirms the presence of water in sunlit zones – a boon for deep space exploration

True, we were pretty certain there was water on the Moon already – but previous observations couldn't distinguish H^2O from its close chemical relative, hydroxyl (OH). Now, thanks to some savvy spectroscopy at the hands of NASA's Stratospheric Observatory for Infrared Astronomy (SOFIA), researchers have been able to confirm the presence of water on the sunlit surface of the moon for the first time (1).

The discovery took place in the Clavius Crater, one of the Moon's largest craters. Previously, it was assumed that the life-sustaining liquid was confined to colder, shadier areas – but this finding hints at water being distributed across larger areas of the lunar surface.

A clever application of existing technology made this discovery possible. "Besides SOFIA, there are no spacecraft with instruments that can make measurements of the Moon at 6 microns," says Casey Honniball, lead author. This is important because a spectral signature at 6 µm is specific to water and is not shared by any other hydroxyl compounds.

"That's why SOFIA is unique," says Honniball. "It flies above most of the water vapor that blocks 6 µm light from ground-based telescopes and has an instrument that can look at the Moon at this wavelength." The modified Boeing 747SP jetliner has a 106-inch diameter telescope that is able to reach above most of the water vapor in the Earth's atmosphere. The onboard FORCAST (Faint Object infrared Camera for the SOFIA Telescope) instrument was then able to pick up the unique spectral signature of water and estimate an abundance of around 100 to 400 µg/g.

It may not be much, but if – as the researchers suggest – the water is trapped in glassy materials or voids between grains sheltered from the harsh lunar environment, it could serve as a potential resource for future space exploration programs. In fact, there are already plans in place to follow up this research with further flights to gather more information about how the water is produced, stored, and moved across the Moon.

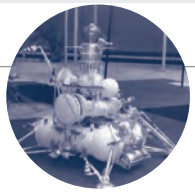
Reference

1. *CI Honniball et al., Nat Astron (2020). DOI: 10.1038/s41550-020-01222-x*

TIMELINE

Lunar Water

Milestones behind the discovery of water on the Moon



1971
The first direct evidence of water on the moon came from Apollo 14 ALSEP – water vapor ions were detected by the onboard MS near the landing site

1976
The Soviet Luna 24 probe landed at Mare Crisium and took samples that contained 0.1 percent water by mass (determined by infrared absorption spectroscopy)

1994
The US Clementine Probe found evidence of ice in a permanently shadowed crater

BUSINESS IN BRIEF

A round-up of the month's business news, from a new method for dioxin determination to saliva testing for COVID-19

- Agilent Technologies has collaborated with SGS to create a new GC-triple quad MS method for the determination of dioxins (persistent environmental pollutants). Now approved by the US EPA, the new method circumvents the need for older and more expensive technology in previous versions (1).
- Thermo Fisher Scientific has announced the election of a new member to its board of directors. Currently CEO of Procter & Gamble's global Beauty business, R Alexandra Keith will bring 30 years of experience in the sector to her new role (2).
- PerkinElmer's SARS-CoV-2 RT-PCR assay has recently received CE marking for saliva samples, with the option to pool up to five specimens from symptomatic or asymptomatic individuals for testing. Not only is it less invasive than the original assay, but it also reduces exposure risk for healthcare workers (3).

R Alexandra Keith.
Image courtesy of Thermo Fisher Scientific.

- Waters Corporation has introduced a new direct mass detector system that will allow lab professionals with minimal MS training to conduct analysis with little sample preparation. The RADIAN ASAP System aims to overcome many of the barriers to entry associxated with traditional MS systems (4).
- Shimadzu has announced its Amyloid MS Service for early, non-invasive screening of amyloid-positive patients in the US. Though only suitable for research purposes, the blood analysis method (based on ICP-MS) can identify suitable individuals for clinical trials and help with the testing of candidate drugs (5).

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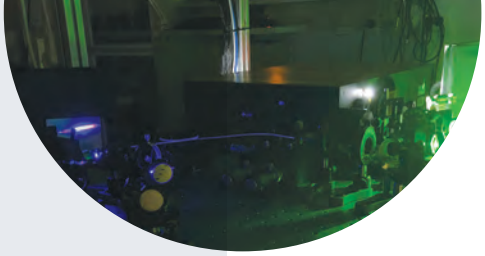
3. *PerkinElmer (2020). Available at: https://bit.ly/2J9yznF*
4. *Waters (2020). Available at: https://bwnews.pr/375fr2B*
5. *Shimadzu (2020). Available at: https://bit.ly/3l2PAx3*



Breaking Records in Gas Detection

A new spectroscopy approach to trace gas impurity detection

Some gaseous impurities can be harmful or indicative of faulty production processes, meaning detection at even trace levels is crucial. A novel interferometric method for background-free broadband absorption spectra measurement and cantilever-enhanced photoacoustic spectroscopy is breaking records in this realm.

Teemu Tomberg dedicated his PhD thesis at the University of Helsinki, Finland to developing advanced light sources and sampling methods that would give unprecedented performance. As he explains:"The acoustic detection method bears some resemblance to atomic force microscopy, but the cantilever is moved by the acoustic waves instead of interaction with the sample."

The applications? Disease diagnosis is one possibility. And Tomberg recognizes the need to present a solution rather than a raw innovation: "Applying these techniques to solving real-world problems is the definite next step."

Reference

1. *The University of Helsinki (2020). Available at: https://bit.ly/35T6WIu*

1998
The Lunar Prospector probe used neutron spectroscopy to determine hydrogen abundance, finding evidence of significant ice trapped in the Moon's craters

2008
India's Chandrayaan-1 spacecraft released the Moon Impact Probe to analyze subsurface debris, finding evidence of water in 650 mass spectra

2018
NASA confirms that its Moon Mineralogy Mapper (M3) showed water ice is present on the surface of the Moon

2020
SOFIA confirms water on the sunlit surface of the Moon with infrared spectroscopy

Ancient Amphora Analysis

A multianalytical approach sheds light on Roman ceramic fragments

Traditionally, the manufacturing processes and provenance behind ceramic materials is studied by interpreting the typology of an object. However, in many cases, this is simply not possible – often because only small fragments are available for analysis. Now, a group of researchers has developed a new, multianalytical method for analysing less than 1 g of ancient pottery shard samples (1).

"Working with small sample sizes is a priority in cultural heritage work," says Gianni Gallello, co-author of the study. "Every fragment that we destroy through analysis is a piece of human history lost forever."

In total, approximately fifty Roman amphorae fragments were studied by multielemental analysis. First, XRF spectroscopy and ICP-MS was used to gain information about the major elements, trace elements and rare earth elements (REE): "The elemental data is important for understanding the provenance of the raw material (clay) and seeing if the pottery was made using different sources – using REE as markers," says Gallello. "On the other hand, the spectra obtained from FT-NIR spectroscopy and voltammetry provided information about the manufacturing processes."

By cross-referencing data from the different techniques, the team were able to identify previously unclassified samples. Though the methods employed in the study are not new, the combination of these techniques and the statistical processing of the obtained data is innovative. "It is always a challenge combining techniques that have never been employed together, but it is also fascinating because it can bring new insights to a particular area of research," says Gallello.

In the future, the team plan to carry out further research in order to expand their database and classify more samples, both in Spain and worldwide.

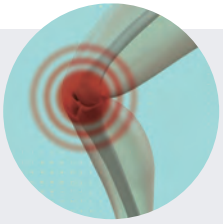
Reference

1. *M Ramacciotti et al., Applied Clay Science, 198 (2020). DOI: 10.1016/j.clay.2020.105857*

Osteoarthritis' Missing Link

Mass spectrometry may help identify reliable biomarkers for osteoarthritis

Osteoarthritis (OA) is one of the most common joint disorders – but its mechanisms are still not fully understood and existing biomarkers lack reliability and sensitivity. This makes it difficult for clinicians to prescribe targeted treatments.



Covering a 20-year period, scientists at the University of South Australia reviewed research that used MS imaging (MSI) to map complex sugars associated with cartilage damage in OA (1). By identifying these molecular mechanisms, the team hope to explain why cartilage degrades at different rates and potentially identify diagnostic biomarkers.

"Diagnosing osteoarthritis has relied heavily on X-rays or MRI, but these provide limited information and don't detect biomolecular changes that signal cartilage and bone abnormalities," said lead author Yea-Rin Lee (2). "Alternative imaging methods such as MSI can identify specific molecules and organic compounds in the tissue section."

Reference

1. *L Sanchez et al., RSC Adv, 6 (2020). DOI: 10.1039/C9RA08225E*

Perplexing Platypus

For the first time, researchers have reported evidence of biofluorescence in a monotreme (egg-laying) mammal under UV light – the eminently odd platypus. The team used fluorescence spectroscopy to analyze a museum specimen and determine which wavelengths of light were being absorbed and re-emitted. In the image above, cyan to green biofluorescence of around 500nm can be seen. Adding to previous studies, the finding raises questions about the ecological function of this extraordinary trait in animals, as well as species ecology and evolution.

Photo credit: J Martin, Northland College; from Anich et al., 2020, Mamalia.

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QUOTE OF THE MONTH

"I always advise people to take risks when they are young – I don't know if I did that enough when I was younger… If you fail, you can always look back and say, 'At least I tried'– and that experience will undoubtedly help you later in life."

By Andrew Whitley, Vice President of Sales and Business Development, HORIBA Scientific, Piscataway, New Jersey, USA.

Take My Breath Assay

Could point-of-care breath tests tighten our grasp on the pandemic?

Rapid distinction of COVID-19 from other respiratory conditions could improve patient care and protect healthcare staff – and a new feasibility study suggests that GC-IMS could be applied to the cause.

Single breath samples were taken from adults presenting to hospitals in Edinburgh, UK, and Dortmund, Germany, with potential COVID-19 and subjected to VOC analysis by GC-IMS. Comparison of the VOC results with RT-qPCR swabs and clinical review demonstrated over 80 percent accuracy for GC testing across sites. Sensitivity was 82.4 percent in Edinburgh and 90 percent in Dortmund; specificity was 75 percent and 80 percent, respectively.

And the tell-tale markers? Aldehydes, ketones, and methanol, according to multivariate analysis. Such approaches could prove a valuable weapon in endemic flu seasons until recent vaccine news becomes a reality.

Reference

1. *DM Ruszkiewicz et al., EClinicalMedicine (2020). DOI: 10.1016/j.eclinm.2020.100609*

In My View

Experts from across the world share a single strongly held opinion or key idea.

Digital Overdose: The New Academic Reality

E-learning and e-communication has swept science amidst the pandemic, but are they worthy substitutes for their physical counterparts?

By Victoria Samanidou, Laboratory of Analytical Chemistry, Department of Chemistry, Aristotle University of Thessaloniki, Thessaloniki, Greece

The COVID-19 pandemic has changed our daily routines. Distancing has put our social lives on hold; remote working has invaded our homes. This is the "new normal": a digital life and a virtual reality.

Few foresaw the rapid spread of the pandemic. But all of us soon faced the reality – and the resulting lockdowns. These lockdowns had far-reaching effects. The impact on academia was obvious, with campuses becoming ghost towns and terrified professors wrestling with unfamiliar online teaching platforms. Sitting at home and speaking into a screen, wondering whether your students are even listening, is quite an experience. And, on the other side, students may struggle to connect to these often very impersonal presentations.

Though teaching from home may sound cozy, it is actually quite tiresome for all involved. The biggest challenge is the lack of interaction with the audience. There's no way for presenters to immediately assess whether the information is being absorbed. And, if it is, to what extent? My own students have admitted that they are easily bored when attending online lectures and webinars; attractive topics or lectures delivered by notably charismatic professors may be exceptions, but they are rare.

Then came the conference changes. Most were postponed for one or two years (the latter currently sounding a little more feasible), but some organizers opted for a digital format. Others opted for a hybrid of physical and digital elements. Unfortunately, those that went fully digital received some negative feedback – particularly from senior scientists. Why? Because virtual events cannot offer the opportunity for connection and collaboration that physical conferences do. After all, we cannot replicate the atmosphere present at coffee breaks and social events, and no one can say for sure when those may return. Yet nobody can deny that digital events have their benefits. If nothing else, we at least save time and money on transport.

Before 2020, I viewed online events with trepidation. But, since March, I seem to have magically overcome this. Now, I find myself not only attending webinars, but even organizing my own events and e-conferences. In fact, 10 days ago we organized a virtual, three-day conference with 18 sessions (some running in parallel), with an audience of over 100 participants from Greece and overseas. Over 200 oral and poster presentations were included, and participants readily asked questions. All admitted that the event was very successful (though we missed coffee breaks and informal chats). It was an awesome experience under current circumstances.

All things considered, remote education is a powerful tool. Take webinars, for example. These events are usually free and anyone can attend – regardless of the locations of hosts or other attendees. With the issue of distances eliminated for the time being, scheduling is also simplified. Nonetheless, I cannot help but wonder to what extent an audience can take in all of the information presented through a computer screen.

I consider myself very lucky that I've had the opportunity to meet many a scientific guru throughout my career – most of whom I encountered at conferences. Their words and lectures have had a significant, positive impact on my career. Perhaps it is still too soon for us to have a clear view on the topic. However, I optimistically think that we should take all the advantages that technology offers us to transform this difficult situation into a positive experience. After all, some changes will likely remain long after the pandemic. So, the "new normal" is truly upon us. Time will tell what impact the lack of these encounters will have on us, and especially on early-career scientists, in the coming months.

The Mother of All Introductory Sampling Textbooks?

This is the resource that aspires to make a real difference to new players in the game of representative sampling

By Kim H. Esbensen, Owner, Chief Consultant, and Independent Researcher at KHE Consulting, Copenhagen, Denmark

"Sampling – is not gambling" - Attributed to Pierre Gy (1924–2015), founder of the Theory of Sampling (TOS).

One may argue that there are more important things to worry about than correct, representative sampling in 2020 (and 2021). But consider the recent breakthrough from scientists investigating how city and municipal sewage systems can be used to monitor the community spread of SARS-CoV-2. And let's not discount the vital interest in false negatives... We are constantly reminded about the importance of the quality of analytical results, upon which critical and vital decisions are made.

Though there are many important factors for a good analytical test (specificity, for one), it is well worth remembering that the preceding sampling uncertainty can be up to a staggering 25 times larger, at worse, when dealing with highly heterogeneous materials. As most of the readers will know, pretty much every material of interest in science and technology is just that: heterogeneous. The only question is to what degree?

For the uninitiated, I answered the question "Why We Need the Theory of Sampling" in a 2014 issue of The Analytical Scientist (1). Boiling down everything I had learned over many years, I offered a poignant summary of my cumulative impressions (apologies for the brashness): "So much homegrown statistics without

"We are constantly reminded about the importance of the quality of analytical results – upon which critical and vital decisions are made."

hardly ever grasping the true and full nature of heterogeneity." Put another way, representative sampling is always important; it is the only way to reduce the highly adverse effects of sampling bias (which is fundamentally different from the well-known analytical bias) and sampling variance. If left unheeded, poor decision-making and grave economic consequences will almost certainly result.

"After two decades of broadening TOS understanding across science and society, I felt inclined to summarize the characteristics of optimal sampling approaches."

After two decades of broadening TOS understanding across science and society, I felt inclined to summarize the characteristics of optimal sampling approaches. A further motive was to offer a partial replacement for my extensive teaching activity (which I love dearly), which will have to be somewhat scaled back after a recent personal upgrade to Esbensen 7.0. It was time to act – to write and to edit.

I certainly had sufficient material (some would say too much) with which to work, having edited and written the Spectroscopy Europe SAMPLING Column for six years (2) – but I wanted to tie everything together with a storyline while adding selected excerpts from relevant didactic features of the TOS FORUM (3). I aimed to provide an introductory book for self-learning and the classroom. However, based on all my four decades of academic experience, it was clear that the standard textbook format could easily become counterproductive with this particular topic (TOS is complex, after all, and not at all "sexy").

Thus, I decided to remove all the usual (and admittedly frightening) mathematics and statistics, instead penning an enthusiastic account of my own story through the gamut of sampling. The right focus, I deemed, should take its point of departure from direct practical matters, but without leaving behind any of the core concepts, rules, and skills – or theory, and with plenty of examples and case histories!

The result was published in February 2020 (4).

Was it a challenge? You bet – but I felt compelled to rise to it. I spent around a year developing preliminary drafts, and I was lucky to receive invaluable help from my good friend Ian Michael (of IM Publications), who would go on to become the book's editor and publisher. Our combined efforts allowed us to attack core questions in an easily understandable fashion, for example: "Why and how can we sample in a documentable fashion that guarantees representativity?"

And were we successful? I'll have to leave that one for readers to decide; but if you are planning on jumping in, please don't wait too long (4). I'm eager for readers' feedback!

But there is a sting in the tale! After a decade-long drought on the TOS scene, I found myself releasing this new offering alongside not one, but two other contenders (5, 6)! Normally, a fierce competition might ensue; however, the other authors are not only colleagues, but also friends. It's my genuine pleasure to acknowledge the Herculean efforts behind two additional textbooks that treat readers to a higher-level use of mathematics and statistics. And, luckily, there is virtually no overlap between these magnum opera and my story. In fact, I'd like to think my introduction will be viewed as a valuable and useful stepping stone into (much) loftier matters if and when one so desires. A useful overview of all three books has been published recently and is freely available, too (7).

All that said, I am willing to wager that my introductory textbook will prove unsurpassed for most newcomers (4). So hello, and welcome to TOS!

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the Analytical Scientist

INNOVATION AWARDS

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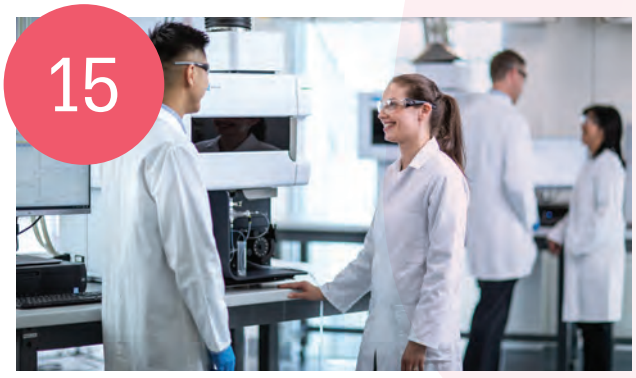
CELEBRATING THE MOST IMPRESSIVE ANALYTICAL TECHNOLOGIES OF THE LAST 12 MONTHS

The Innovation Awards are back for 2020! Once again, we encouraged nominations for the analytical technologies and solutions most likely to make waves. Our judging panel, made up of select experts from across the analytical community, were then tasked with reviewing the submissions and ranking the Top 15.

Congratulations to those who made the cut! Think you know who the winners might be? Don't dally – see for yourself!



POLYCHROMATOR SYSTEM FOR AN ATOMIC SPECTROMETER

A polychromator design that improves the analytical performance of an atomic spectrometer

Produced by Agilent Technologies, Inc.

The redesigned polychromator has reduced detection limits by approximately 40 percent, improving spectral resolution. Thus, lower concentrations of elements can be measured using ICP-OES, and the incidence of spectral overlap is reduced. The design changes have also reduced the focal length of the polychromator by 40 percent – a reduction that results in a smaller instrument, reducing both electricity and gas consumption.

Potential impact

Recent patent-pending polychromator design changes have improved the analytical performance of ICP-OES. These improvements were achieved through redesign of the collimating mirror and inclusion of an aperture mask. Traditionally, the mirror had a spherical or parabolic concave surface that limited light focusing onto the detector. By changing the mirror surface to be freeform, the effects of optical aberrations have been significantly reduced, vastly improving focusing.

A serrated mask was also added to the polychromator aperture to reduce erroneous background signal, which can impact instrument sensitivity. The first instruments to include this new polychromator design were the Agilent 5800 and 5900 ICP-OES, released in November 2019.

What the judges say…

It is impressive to see how a change from traditional to freeform optics can have a large impact on instrument size and resource consumption.

ANALYTICAL MODULE FOR AN ELECTRONIC LAB NOTEBOOK

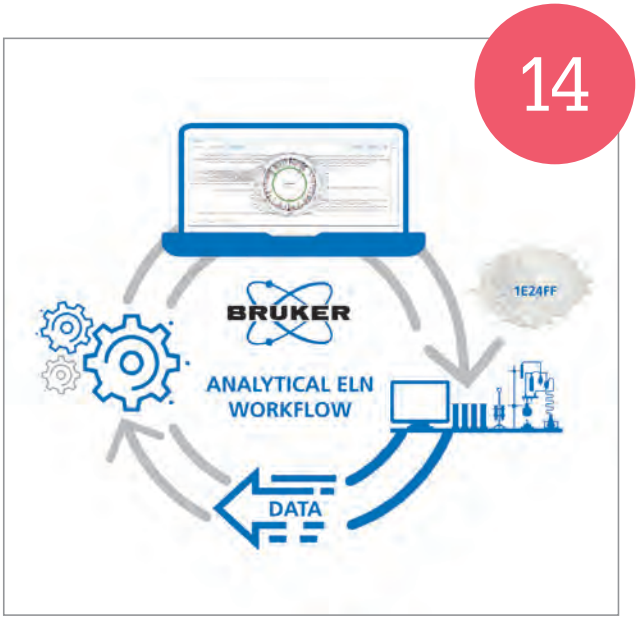
Automates instrument data collection and enables data access almost simultaneously to analysis

Produced by Arxspan, a Bruker company

Data management is a major efficiency challenge for analytical labs. For the first time, the user-friendly, cloud-based module for an electronic lab notebook enables scientists to automatically capture, analyze, centralize, and share instrumentation data and results. It is broadly suited for use with analytical techniques that generate multitudes of spectral analysis and other types of QC data, such as MS and NMR. The centralized data acts as a reference database for synthesized compounds and impurities.

Potential impact

Put simply, the product aims to increase efficiency in the analytical lab. The module removes redundant manual steps, such as copying and pasting data from instruments to shared drives. Automated data retrieval then reduces bottlenecks and significantly reduces the amount of time invested by researchers in data management, while also reducing the risk of transcription errors.



12

THE MASSBOX

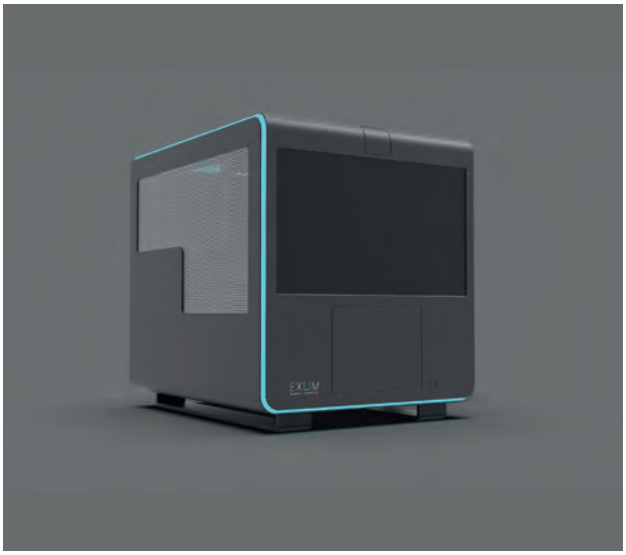
Approachable organic and inorganic quantification where you need it

Produced by Exum Instruments Inc.

The Massbox offers a step change in solid sample characterization. As the first commercial instrument combining both laser ablation and laser ionization under vacuum in the same analytical session, it improves the ease and quality of analysis. As a result, the end user requires fewer instruments to assess a larger range of elements and organic compounds – all without the need for difficult and time-consuming sample preparation. The simplified analytical process means that anyone on the team can run the tool quickly and easily, spending less time collecting the data and more time solving problems.

Potential impact

The impact is the reason for the Massbox's development. Jeff Williams, Exum Instrument's CEO and Founder, left academia to build this tool because of his frustration with the present state of analytical equipment. The Massbox has dramatically reduced many barriers to entry – including cost, ease of use, reliability, and instrument size – for several industries. Whether you are a cannabis producer, metal fabricator, or battery developer, you can now quickly assess your materials and shorten the development and quality control cycles of any solid material on site.



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LASER CRYOSTUCK LABELS

Laser-printable cryogenic labels that stick to frozen vials

Produced by GA International

CryoSTUCK was originally designed for thermal-transfer printers in roll formats. After overwhelming demand from our customers, a laser-printable version of CryoSTUCK in sheet format is now available for desktop laser printers. These labels are intended for the labeling and relabeling of tubes and vials already stored in liquid nitrogen or low-temperature freezers.

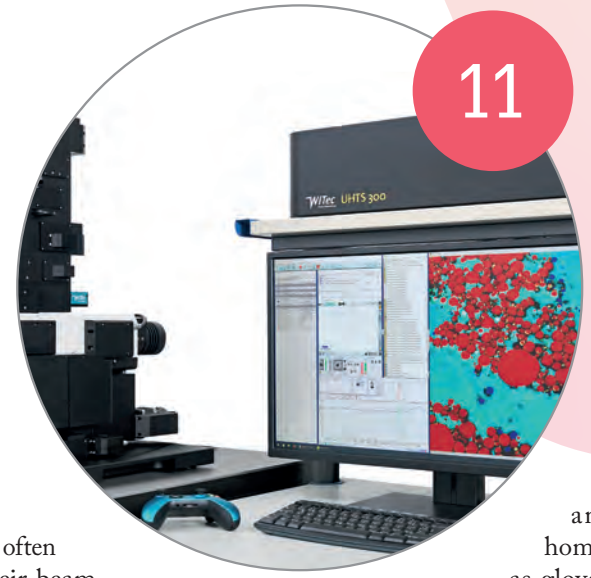
Potential impact

With an adhesive designed for frozen surfaces, the CryoSTUCK labels can be applied to containers with a temperature as low as -80°C; there is no longer a need to thaw samples before relabeling. Once affixed, they can be immediately re-stored in cryogenic conditions (in temperatures as low as -196°C).

What the judges say…

A significant time saver….

11



WITEC ALPHA300 APYRON

A Raman microscope capable of self-optimization and remote operation.

Produced by WITec GmbH

Advanced Raman imaging experiments often include many optical elements in their beam paths. The fully automated alpha300 apyron Raman microscope features motorized opto-mechanical components controlled by an integrated software suite that can optimize their alignment with algorithm-driven routines. Remote operation is also possible, and modularity of the components allows system reconfiguration as experiments evolve. These innovations make the technique more accessible than ever before, while enhancing performance by accelerating setup for increased sample turnover rates and ensuring the consistency and repeatability of results. Researcher workloads are also substantially reduced as less input is required and sources of error are minimized.

Potential impact

Raman microscopy is a routine analysis tool. Automation has been key to broadening the technique's appeal, and the alpha300 apyron promises to accelerate this trend. How? By automating optical alignment and enabling operation from home offices or in enclosures, such as glove boxes. Only the mounting of the sample on the microscope stage requires physical interaction. Remote operation is particularly useful for researching materials grown under very controlled conditions or when dealing with potentially hazardous biological samples.

What the judges say…

Full automation and self-optimization of the Raman imaging process allows even unexperienced researchers to get the best possible results.

IONICON PTR3-TOF 10K

High-performance PTR-TOF for detecting highly oxygenated organic molecules

Produced by Ionicon

The PTR3-TOF 10K represents a new generation of PTR-TOF systems optimized for the detection of highly oxygenated organic molecules and RO_2 radicals. The fundamental invention behind PTR3 is the decoupling of ion-molecule reaction chemistry from the axial transport of reagent and analyte ions. This decoupling significantly increases the reaction time and boosts instrument sensitivity up to more than 50000 cps/ppbv. The instrument comprises a triple ion source for seamlessly selecting different reagent ions and an advanced inlet system for virtually contact-free sample introduction. The result: minimized sampling losses for reactive organic molecules.

10

Potential impact

The PTR3 facilitates quantitative detection of volatile organic compounds and their oxidation products, including highly oxygenated organic molecules – down to ppqv levels. The new concept of contact-free sampling allows the detection of organics of virtually all volatility classes. The performance of the PTR3 even enables RO_2 radical quantification as well as the study of compositions and concentrations of secondary organic aerosols. These molecules are known to play a vital role in cloud formation and are central to advanced climate research efforts.

What the judges say…

The Ionicon PTR-MS technology is the "gold-standard" in real-time measurement of volatile organic compounds in many application areas.

9

MET ONE 3400+

Fully automated and portable air particle counter optimized for environmental monitoring workflow improvement

Produced by Beckman Coulter Life Sciences

The MET ONE 3400+ enables automated routine environmental monitoring, reducing human error and improving data integrity. How? By automating the user's SOP inside the counter and including an interactive SOP sampling map on the portable counter screen. The technician simply taps sample locations on the interactive map; the counter does everything else. It configures itself in accordance with the SOP, takes the air sample, and creates an electronic record right there and then, eliminating many of the manual steps involved in environmental monitoring. The MET ONE 3400+ can also use a barcode scanner to scan the active air and settle plate IDs deployed at each location for inclusion in the electronic record. Microbial colony-forming unit counts and species can be added to the electronic record once the plates have been incubated.

Potential impact

MET ONE automates the sampling process. It removes the risk of manual errors and speeds up workflows. It has made printing reports a thing of the past. Once sampling locations have been determined, all the user has to do is upload the map showing sample locations into the counter to create an onscreen, interactive sampling map; you only need to do this once. Thereafter, it simply becomes an electronic, onscreen, interactive guide every time sample monitoring takes place.

What the judges say…

Elimination of human error by automating the sampling process and data analysis should be routine workflow!

8

IMSCOPE QT IMAGING MASS MICROSCOPE

An imaging mass microscope that combines qTOF MS with optical microscopy

Produced by Shimadzu

The Shimadzu iMScope QT platform combines the visualization of optical microscopy images with compound distribution and identification information from MS, allowing target compound distributions in microscopic regions to be visualized and characterized. For example, when looking at a cancer tissue sample with a microscope, the application of quantitative information about anti-cancer drugs from MS makes it possible to study drug delivery and efficacy. Notably, the mass spectrometer and microscope units can be easily uncoupled, allowing for the connection of an LC system, if needed.

Potential impact

Global demand for fast, high-precision mass imaging technology has extended from a core of pharmaceutical and medical applications to diverse fields, including agriculture and food science. The iMScope QT was engineered to meet those new expectations – while still offering exciting opportunities in clinical pathology, tissue imaging, biomarker discovery, and functional metabolomics.

What the judges say…

A big benefit of the iMScope QT Imaging Mass Microscope is that it can be used in the imaging mode as well as in LC-MS mode, allowing for use in a wide range of applications.

7

THERMO SCIENTIFIC VANQUISH CORE HPLC SYSTEMS

An advanced LC system for optimized routine testing workflows

Produced by Thermo Fisher Scientific

The Thermo Fisher Scientific Vanquish Core HPLC Systems provide pharmaceutical, food, and industrial laboratories with improved productivity, precision, and compliance in their analytical workflows. The instrument's ability to automatically monitor and determine solvent and waste levels and continuously monitor system health minimizes downtime and reduces delays. These features are of significant benefit in laboratories performing routine analyses, where the high throughput of accurate results is paramount to success.

To further streamline analytical processes, method transfer is simplified through custom injection programs, tunable gradient delay volume, and a choice of temperature regulation technique. These innovative features allow simple method transfer across instruments while ensuring consistent results. The Vanquish Core HPLC Systems also provide an intuitive user interface that facilitates precise result delivery (regardless of operator experience) and offers simple integration with all major CDS software.

Potential impact

Routine testing and quality control workflows are essential in product development and manufacturing. The timely delivery of accurate analytical results ensures that global supply chains are not disrupted and people have access to the food and drugs they need. Through its focus on the provision of consistently dependable results at a high throughput and streamlined processes, the Vanquish Core HPLC Systems allow greater analytical productivity that meets increasing global demands without increasing pressure on operators.

6

NANODIS SYSTEM

Provides formulation scientists with accurate drug release profiles of nanomedicines

Produced by Agilent Technologies

Current testing techniques present formulation chemists with significant challenges when measuring accurate release profiles of drug-loaded nanoparticles – a critical step in drug development and manufacturing. Nanoparticles can block or even rupture the filters and membranes used in the testing process, resulting in erroneous drug release profiles with dire consequences.

NanoDis is a simple, effective solution that uses cross-flow filtration, rather than traditional "dead end" filtration. This concept, traditionally used in industrial process chemistry, has been combined with conventional USP compliant dissolution apparatus. Plus, the whole workflow is automated, using established software already used in environments requiring 21 CFR part 11 compliance. Think of it as a go-to solution for compliant nanoparticle dissolution testing.

Potential impact

Nanoparticle drug dosage forms are essential to improve patient lives (by reducing drug side effects) and patient outcomes (by improving drug solubility and bioavailability), especially in oncology and cardiology. Dissolution testing is a critical regulatory requirement for the development of medical drug dosage forms as well as the manufacturing and QC testing before release to market. The NanoDis System enables R&D formulation chemists to get their best new drugs into manufacturing faster, and the manufacturing teams to deliver consistent batches of QC-passed drug products for the market – all in an automated and complaint manner.

5

THERMO SCIENTIFIC ORBITRAP EXPLORIS 240 MASS SPECTROMETER

A new-generation high-resolution mass spectrometer for research and high-throughput analyses

Produced by Thermo Fisher Scientific

The Thermo Scientific Orbitrap Exploris 240 MS helps drive discovery and identification with increased accuracy, allowing researchers to confidently accelerate the translation of discoveries into clinical applications. The system delivers mass accuracy, precision, sensitivity and resolving power across a wide dynamic range for research and high-throughput proteomics, metabolomics, biopharmaceutical characterization, and small-molecule analyses.

With new-generation architecture and powerful control software functionality, the Orbitrap Exploris 240 MS provides simple yet optimal data acquisition and processing capabilities, addressing the most demanding analytical challenges. Furthermore, the system's operational simplicity and fast scan capability help streamline time to results. Importantly, the system offers positive/negative mode switching for comprehensive sample coverage, while the built-in Thermo Scientific AcquireX intelligent data acquisition workflow enables greater automation for structural identification and characterization of small molecules. The Orbitrap Exploris 240 MS is also fully compatible with the Thermo Scientific FAIMS Pro interface, achieving enhanced identification of proteins and peptides.

Potential impact

Proteomics, metabolomics, biopharmaceutical characterization, and small-molecule scientists are seeking technologies that can streamline and speed proteomics studies to clinical applications, reduce time to market for candidate biotherapeutics, and address the growing challenge of characterizing novel chemical entities in small-molecule studies. The Orbitrap Exploris 240 MS delivers the high performance and versatility needed to meet these needs and drive productivity enhancements. The system also delivers high reproducibility in mass accuracy and peak integrated area over several sample batches and several days of acquisition, enabling minimum post-acquisition data manipulation to yield high-quality results – a must in large-scale metabolomics projects.

4

CULPEO QCL-IR LIQUID ANALYZER

Laser-based mid-infrared liquid analyzer for real-time biophysical characterization

Produced by DRS Daylight Solutions

The advent of quantum cascade laser (QCL) technology enables real-time biophysical characterization in the mid-infrared fingerprint region for the first time. With a spectral brightness that far exceeds traditional light sources – even synchrotron – our QCL-based liquid analyzer provides transmission measurements at path lengths far exceeding those achieved by FTIR-ATR. This approach allows for multi-parametric, non-destructive characterization of samples in real-time and over broad concentration ranges, without the need to dilute the sample. By providing real-time information on concentration, higher order structure, and the ability to monitor bioconjugation reactions, the Culpeo analyzer enables industry to advance towards real-time release. With a purpose-built design that facilitates its use as a process analytical technology (PAT), the Culpeo paves the way to continuous manufacturing of biologic drug substances.

Potential impact

Traditionally, quantitative characterization of proteins and protein conjugates in aqueous environments has been an extreme challenge in the fingerprint region of the mid-infrared spectrum. Because of limited spectral brightness, most workhorse technologies using mid-infrared suffer from limited detection and long sampling times. Therefore, scientists have historically relied on off-line techniques for mid-infrared characterization of biological analytes in aqueous media. The laser-based Culpeo surpasses the limit of detection commonly experienced with traditional mid-infrared techniques and provides chemical information that is otherwise unobtainable via UV methods. Welcome to real-time, non-destructive analysis of biologics for in-line and at-line workflows.

3

HPIMS (HIGH-PERFORMANCE ION MOBILITY SPECTROMETRY) FOR PROCESS ANALYTICAL TECHNOLOGY

HPIMS reduces analysis time from days to minutes, reducing cost and increasing efficiency

Produced by Excellims Corporation

HPIMS brings the power of state-of-the-art ion mobility out of the lab, enabling high resolution and sensitive chemical detection at the point of need. Innovation comes in lots of shapes and sizes, but is meaningless if it cannot be applied. HPIMS makes the application of IMS easy and accessible.

Currently, users must purchase a mass spectrometer with integrated IMS to benefit from ion mobility. Along with high cost, traditional integrated instruments are operated under vacuum and are therefore tied to a lab bench. HPIMS liberates the technique from vacuum pressure, bringing the technique to the point of risk and into the hands of operators who need the highest quality chemical detection where it is needed most: at line.

Potential impact

The potential of HPIMS is huge: low-cost, high-performance, and agile chemical detection for everyone, everywhere.

There are three HPIMS-based instruments. The first provides IMS-based chemical detection at the point of risk in minutes. Particularly suited for applications such as cleaning validation on pharmaceutical production lines, the GA2200 is the only standalone HPIMS instrument designed for the GMP environment. Second is a rugged, portable, and integrated HPIMS-mass spectrometer (MC3100) that uses two-dimensional chemical detection to address unmet field detection challenges. The HPIMS also enables ion mobility to be added to a lab for six figures, rather than seven. The MA3100 is a standalone HPIMS that can be added to an existing mass spectrometer.

TIMSTOF FLEX MALDI-2

An enhanced MALDI technique linked to Bruker's timsTOF fleX instrument

Produced by Bruker Daltonik GmbH

Originally developed by Klaus Dreisewerd and Jens Soltwisch at the University of Muenster in 2015, MALDI-2 uses laser-based post-ionization to enhance and enrich the MALDI experiment. The advance provides access to chemical classes typically opaque to MALDI – and at unprecedented sensitivity (2–3 orders of magnitude compared with traditional MALDI). Though post-ionization significantly boosts ion yields for many different analytes and reduces the ever-challenging ion suppression effects in MALDI imaging, it also results in increasingly complex spectra. MALDI-2 was implemented in the timsTOF fleX with a view to unravel these complex molecular compositions. Trapped ion mobility spectrometry (TIMS) unleashes the full potential of MALDI-2 by separating the complex mixture of masses by m/z and ion mobility (collisional cross section). By treating complex spectra with deconvoluted feature assignment, TIMS can find larger numbers of features and enable confident compound identification via comparisons with LC-PASEF data or database matches.

2

Potential impact

MALDI-2 overcomes several limitations of the original MALDI experiment. The greatest impact will potentially be found in pharma. For DMPK studies, where drug-dosed tissue needs to be analyzed, industry bodies can avoid "overdosing" animal models to explore physiological relevant concentrations and their effects on metabolism in vivo.

The chemical information obtained by MALDI-2 and TIMS also allows for detection of complex lipid profiles and their localization. The intense ion suppression effect of phosphatidylcholines in traditional MALDI is reduced with MALDI-2, which provides access to a wider range of compound classes. This will have a marked influence on clinical biomarker discovery.

NEXION 5000 MULTI-QUADRUPOLE ICP-MS

The NexION 5000 is the industry's first four-quadrupole ICP-MS system

Produced by PerkinElmer, Inc.

PerkinElmer's NexION 5000 Multi-Quadrupole ICP-MS is a four-quadrupole instrument designed to remove the most complex interferences and address the most challenging applications for trace elemental testing. It takes ICP-MS performance beyond high-resolution ICP-MS and traditional triple-quad technology to deliver part-per-trillion background equivalent concentrations (BECs).

Unlike triple-quad systems, the NexION 5000 ICP-MS delivers four stages of mass separation. A focused ion beam is introduced into the ion optics, enabling the user to control the fate of interferences as early in the process as the quadrupole ion deflector. Here, the ion beam is shaped and directed before mass is filtered in Q1. The ions then enter the quadrupole universal cell with dynamic bandpass tuning, which controls the reaction and eliminates reaction by-products before they have a chance to form new interferences. The resulting ions are mass separated in Q3 before detection.

Potential impact

By combining proprietary technologies, the NexION 5000 Multi-Quadrupole ICP-MS system can deliver less than 1 ppt BECs – even under hot plasma conditions – for alkali and alkali earth elements. When it comes to trace elemental testing in challenging application areas such as semiconductor device fabrication, instrumentation is required to be able to detect at the lowest possible concentrations to reduce field failures of semiconductor products. In the health sector – especially biomonitoring, where inaccurate results in complex matrices can make all the difference in a patient's diagnosis and treatment – the importance of such low limits of detection cannot be overestimated.

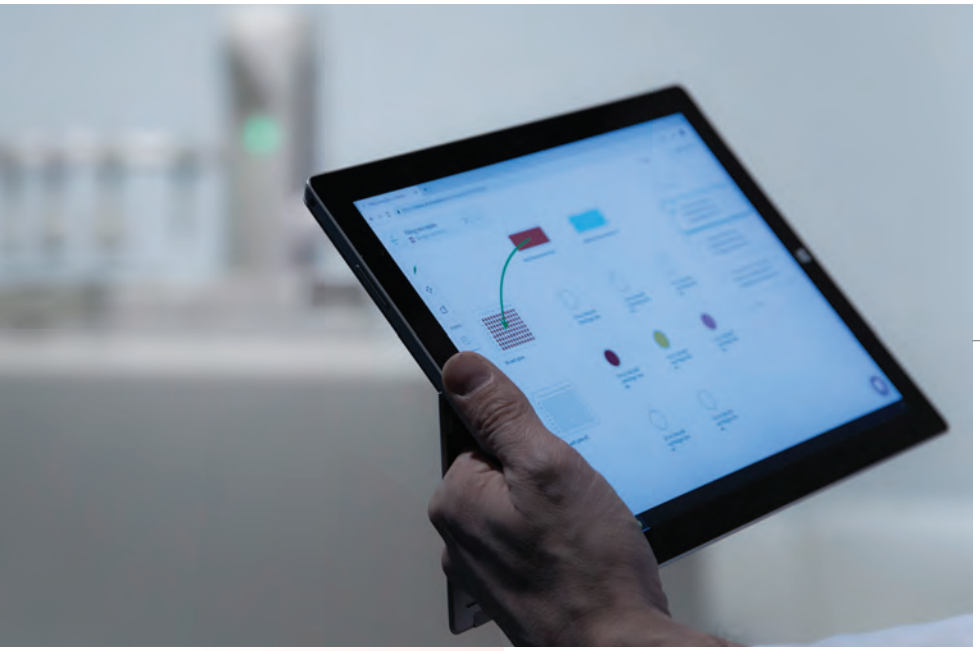
What the judges say…

The NexION 5000 Multi-Quadrupole ICP-MS delivers ultra-high sensitivity in challenging applications such as the analysis of ultra-pure water, trace elements in blood or air pollution monitoring.

the Analytical Scientist

THE INNOVATORS

SHOWCASING THE PRODUCTS AND COMPANIES MAKING A DIFFERENCE IN 2020



THERE IS ONLY ONELAB

Enabling easy, remote set-up and operation of versatile liquid handling solutions

OneLab is a unique, browser-based software environment that allows researchers to design and share their own protocols through a highly intuitive graphical interface. This can be done step-by-step from any PC or tablet, via either the cloud or a standalone server. It can also be used with current set-ups and no further connected devices are needed.

Design protocols:

- Intuitive graphical drag-and-drop design interface
- Eliminate error-prone calculations for serial dilutions and concentration normalizations
- Accelerate collaboration and training by easily sharing protocols with other researchers

Execute experiments:

- Ensure correct manual execution of protocols with your current set-up
- Guarantee reproducibility with secure communication of protocols to OneLab-compatible device(s).
- Connectivity with Andrew+ and Pipette+, or any other connected device, enabling researchers to achieve the highest levels of repeatability and productivity, with the added advantage of full traceability.

Go to https://onelab.andrewalliance.com today and try out OneLab for free.

ASK THE EXPERT

Nigel Skinner PhD, Head of Marketing, Andrew Alliance, Geneva, Switzerland

Andrew Alliance is a shining example of "innovation" in all respects. Accordingly, we have been recognized for this through numerous awards since our founding in 2011, most recently including an award from the Swiss Institute for Quality Testing (October, 2020), a product leadership award from Frost & Sullivan (Sept, 2019) and New Product Innovation Awards from the Society for Laboratory Automation & Screening (Feb 2019).

What trends are driving innovation in the field?
The drive to deliver precision medicine and translational research places ever higher demands – and standards – on research, with expectations on evermore precise data. This requires superior productivity, with greater precision and less errors, and drives innovation in workflow execution.

How has COVID-19 impacted your ability to innovate in 2020?
Andrew Alliance has supported customers developing COVID-19 vaccines, as well as both serological and PCR-based tests, throughout lockdown. Those customers have appreciated our cloud-native software for the remote set-up and operation of our liquid handling automation from, from example, their home office. Moreover, it has emphasized the benefits of our unique approach to innovation – an agile development process capable of rapidly translating innovations into products that can be installed, trained and supported remotely.

MET ONE 3400+ AIR PARTICLE COUNTER

Automates and simplifies routine environmental monitoring for GMP cleanroom compliance by integrating innovative features "all inside the box"

The new MET ONE 3400+ enables users to import routine environmental Standard Operating Procedures (SOP) into the counter, creating an interactive SOP map on the counter screen itself, which guides technicians to each sampling location. It automatically configures the counter according to the user's SOP, which helps reduce human error and improve data integrity.

All electronic records inside the counter are reviewed and approved — using electronic signatures — via a web browser, then exported via Ethernet. Administrators can also manage SOP version control remotely through a web browser.

"Because everything is 'in the box,' managing even complex SOPs can be greatly simplified," says Carter Moursund, Senior Product Manager. "Using a web browser interface, QC professionals can customize their electronic SOPs and maps, and change or update them quickly and easily. Plus, thanks to a new 'plug-n-play' networking feature, all SOP modifications are automatically replicated on all counters in use."

Interactive, on-screen tracking instantly shows on-site users which locations have been sampled, allowing them to monitor their progress at a glance.

After on-site monitoring, professionals then "sign" sampling reports via electronic signature. Reports can be exported in a secure electronic format to their network or a USB device. Thus, the MET ONE 3400+ supports compliance with the FDA's 21 CFR Part 11 regulation, and can streamline data access during audits required to maintain GMP manufacturing status.

"We're serious about ensuring data security and integrity," Moursund says. "All data produced by the instrument are encrypted, and users are never permitted to delete sampling records for any reason.

"And we're just as serious about making the new 3400+ model even more user-friendly. We designed it to be light so it's easier to carry from location to location. Plus, the 10-inch touchscreen is highly sensitive, so data entry can be trouble-free – even when users are double-gloved.

"To help simplify cleanroom monitoring for FDA and GMP compliance," he says, "we've not only put a lot of valuable time-saving features into the box, but we've also made the box itself easier to use, carry and clean."

For more information, visit beckman.com/metone.

THE LUMOS II FTIR IMAGING MICROSCOPE

LUMOS II is a fully automated, stand-alone FTIR imaging microscope

The LUMOS II takes FTIR microscopy to the next level by improving the speed, ease of use, accuracy and reliability. Beginners get perfect results in no time, while experts are afforded almost unlimited possibilities.

... FTIR Microscopy?

Conventional microscopy is one of the most widespread analytical techniques in research, forensics, failure analysis, life science and electronics. FTIR improves the precision and power of this tool for comprehensive microanalysis, allowing you to detect and immediately characterize tiny particles, product defects or tissue anomalies. Infrared spectroscopy gives abundant molecular information on organic and inorganic materials alike. The result: simple analysis of any sample type of any origin.

… FTIR Imaging?

The LUMOS II features incredibly fast FTIR imaging. Every pixel of an FTIR image comprises an entire FTIR spectrum. This spectral data can be used to render a false color image that emphasizes sample properties, like chemical structure or composition, giving superb spatial resolution and peak sensitivity across measurement modes. Researchers can assess the homogeneity of many materials (including tablets and polymers) and chemically characterize contaminations with ease and precision.

... LUMOS II?

LUMOS II naturally delivers leading performance in transmission, reflection and attenuated total reflection (ATR) measurements. It is also fully automated, software-controlled, and features an easily accessed sample stage. The retractable ATR crystal is controlled by high-precision piezoelectrical motors that facilitates an unhindered view of the sample while guaranteeing that measurements are taken precisely where you want them. The integrated pressure simultaneously ensures appropriate sample contact over entire samples.

Also on offer: exclusive FPA imaging technology that exceeds the speed and spatial resolution of line array and single-point measurements with enormous applicability. High-quality spectral data are obtained rapidly with ease and comfort. Whether it be transmission, reflection or ATR, the LUMOS II is always the right choice.

Learn more about LUMOS ll: www.bruker.com/lumos

FAST, ACCURATE, AND QUANTITATIVE VALUES

Accurately measuring trace or residual pesticides in agricultural materials and trace levels of regulated chemicals in tap water

The JMS-TQ4000GC Triple-Quadrupole Mass Spectrometer accurately measures trace or residual pesticides in agricultural materials and trace levels of regulated chemicals in tap water, and simplifies quantitative analysis of persistent environmental pollutants such as dioxins and PCBs. It achieves the fastest selected reaction monitoring switching speed in the industry at 1,000 channels per second. Chemists can analyze multiple target compounds with high accuracy.

The JMS-TQ4000GC offers three distinct technologies for high-speed analysis: ion accumulation, the short cell, and a fast GC technique. The short collision cell accumulates ions and ejects them in rapid pulses; the noise level of the signal is reduced by synchronizing the timing between pulsed ion ejection and signal acquisition, facilitating high-sensitivity analysis. A short and narrow capillary column with a rapid oven temperature ramp then allows the TQ4000GC to expedite routine analysis by reducing the time needed for measurements. The short collision cell technology provides enough high-speed transitions for fast GC measurement without any sensitivity loss.

Easier and faster data analysis

With an easy-to-read layout and simple operation, the TQ4000GC data analysis software "Escrime™" was developed for simultaneous multi-component analysis. Chromatograms are arranged in a vertical column, making it easy to compare samples. Combined with the compound "slideshow" function, the Escrime software makes it easy for chemists to confirm all samples and components.

A wide range of organic analyses

In addition to the standard electron ionization source, the JMS-TQ4000GC also supports optional chemical ionization and photoionization sources, enabling easy acquisition of molecular weight information. The system is also not limited to just GC-MS. It can conduct two types of direct probe experiments: direct insertion probe for insoluble compounds and direct exposure probe for high-boiling-point and labile compounds.

To learn more, please visit: https://bit.ly/37sIbCm

EVOLUTIONS IN ANALYTICAL SAMPLE PREPARATION

Evolutions in Analytical Sample Preparation

Chemical compatibility, binding, extractables and column life are critical in HPLC sample preparation. The quality of the membrane used to filter your samples has a direct effect on these factors, so selecting the right membrane is paramount to producing consistent, reliable results.

Water-wettable PTFE (wwPTFE) is a hydrophilic, chemically inert membrane designed specifically for chromatography. Developed as an all-purpose membrane for aqueous, acidic, basic, non-aggressive organic, and aggressive organic solutions, the wwPTFE membrane offers minimal protein binding and low levels of UV-absorbing extractables.

wwPTFE is offered in syringe filters, centrifugal devices, multi-well filter plates, and standalone membrane discs. Many of these devices incorporate a glass-fibre prefilter for the efficient filtration of high-particle-laden samples.

For more information on analytical sample prep, visit pall.com/lab

ASK THE EXPERT

Craig Tamble, Applications Scientist, Pall, Westborough, Massachusetts, USA

How does your company embody "innovation"?

From new products to exciting applications, innovation is integral to our mission at Pall. This is evident in our reaching out to new industries, like cannabis testing, to support the analytical capabilities of emerging fields from the beginning. Our expansive filtration device portfolio can help with purification and isolation, giving companies a total solution from start to finish.

Have you learned any valuable lessons to carry forward from this difficult year?

Communication has always been important. This year, with researchers separated from their labs, it has been more important than ever. Reduced lab time also put a premium on more focused experiments and faster results. Working in a more collaborative way with our customers is something that I look forward to continuing in the future.

What is your prediction for the future or analytical instrumentation?

Analytical instrumentation is becoming faster, smaller, and more sensitive, which places even greater emphasis on properly filtering samples. Clean and retentive filters are essential when it comes to keeping instruments running smoothly. How: by removing all particulates that could block columns and tubing while ensuring consistent baselines and low backgrounds for optimal detection of analytes.

NEXION® 5000 MULTI-QUADRUPOLE ICP-MS

The industry's first four-quadrupole ICP-MS, delivering superior interference removal, excellent stability, and unmatched matrix tolerance

PerkinElmer's NexION® 5000 Multi-Quadrupole ICP-MS is a four-quadrupole instrument designed to remove the most complex interferences and address the most challenging applications in trace elemental testing. It takes ICP-MS performance beyond high-resolution ICP-MS and traditional triple-quadrupole technology to deliver exceptionally low part-per-trillion (ppt) background equivalent concentrations (BECs).

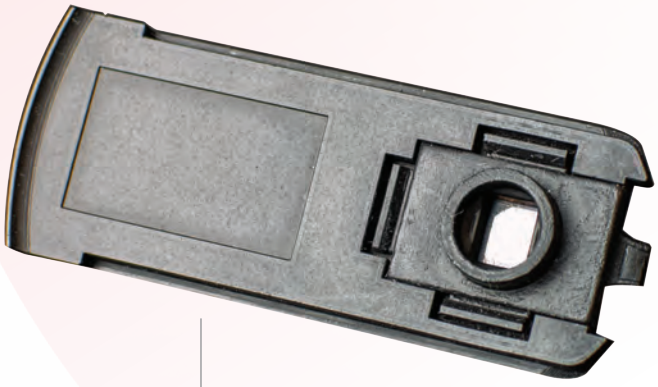
Unlike triple-quadrupole systems, the NexION 5000 ICP-MS delivers four stages of mass separation: a clean, focused ion beam of the mass of interest is introduced into the ion optics, enabling control of the fate of interferences as early in the process as the quadrupole ion deflector (Q0), where the ion beam is shaped and then directed to Q1 (first transmission analyzer quadrupole). Mass separation takes place here. The on-mass ions then enter the quadrupole universal cell (Q2), where dynamic bandpass tuning controls the reaction and eliminates reaction byproducts before they have a chance to form new interferences. The resulting ions are mass separated in Q3 (second transmission analyzer quadrupole) before detection. This unique design makes the NexION 5000 the only ICP-MS to not only offer fine control over what enters the cell but also the reaction within the cell, delivering superior interference removal.

Plus, the novel second-generation triple cone interface with patent-pending OmniRing™ technology was developed with both sensitivity and stability in mind, providing a seamless solution for reducing space-charge effects.

The combination of these and other tried-and-tested proprietary technologies allows the NexION 5000 ICP-MS to deliver less than 1 ppt BECs (even under hot plasma conditions) for alkaline and alkaline earth elements, as well as ppt BECs for non-metals, such as sulfur, silicon and phosphorus. This is key for ultra-trace elemental analyses in challenging application areas. For example, instrumentation used in semiconductor device fabrication needs to be capable of detecting the lowest possible concentrations to reduce field failures of semiconductor products. And, in the health sector, especially biomonitoring, inaccurate results can make a great difference regarding patient diagnosis and treatment.

PerkinElmer's NexION 5000 Multi-Quadrupole ICP-MS delivers performance to the power of four.

To learn more about the unique benefits of the NexION 5000 ICP-MS, download the interactive brochure and application notes at www.perkinelmer.com/nexion5000



THE ARROW™ ATR SLIDE

A silicon ATR consumable slide with zero cleaning, zero risk, and zero hassle: a new direction for ATR

Designed for the Quest ATR accessory, Arrow™ facilitates the rapid assessment of a range of liquid analytes. Sample batches can be prepared away from the spectrometer on sample slides made from recycled polypropylene, reducing sample handing and boosting productivity.

Key features include:

- Ultra-thin silicon wafer ATR
- Batch preparation of samples ex situ
- No cleaning required
- Archivable samples
- Retrofittable to all existing Quest™ units
- Supplied volatiles cap

The Arrow™ was developed to tackle two key analytical problems. The first is cleaning of the puck between samples – this can lead to cross-contamination and wasted time for time- and resource-limited labs. The second is difficulty analyzing samples like paints and glues, which are sticky and difficult to remove, causing issue in traditional ATR experiments. As for applications, the Arrow™ has uses across microbiology, clinical research, paints and glues, and forensics.

For more information, please visit: https://www.specac.com/en/

SPECAC STRIKES AGAIN: INCITING INNOVATION

The design team at Specac has developed another blockbuster accessory for its market-leading Quest ATR

Specac lives to innovate. As we approach our 50th birthday in April 2021, we continue to apply our chief focus to bringing new products to market. We have led the way in developments for molecular and elemental spectroscopy for chemical analysis, and were the first to market with the monolithic diamond, single bounce, Golden Gate ATR in 1994. The Quest ATR, launched in 2012, was the first of a new generation of accessories, and is now the best-selling ATR on the market.

FTIR has seen a burgeoning use in medical screening, diagnostics and analytics in the last few years, and we believe we can make a real difference in this market with our existing and new products. To this end, we've significantly increased our technical competence in recent years by appointing two experienced applications scientists.

SÉBASTIEN ROUZEAU

Product Manager for GPC/SEC systems and Detectors
Tosoh Bioscience GmbH, Griesheim, Germany

What was your route into analytical science?
As PhD student in polymer science, I had to characterize complex macromolecules by size-exclusion chromatography coupled with light scattering and viscometry detection. I spent countless hours understanding the theory, developing appropriate experimental conditions and getting the most relevant results out of the data I obtained. My passion for this very specific analytical technique arises from those times and motivates me to this day.

What development are you most proud of?
I am extremely proud of Tosoh Bioscience's LenS3 MALS detector for the characterization of molecular weight and size of biomolecules and polymers. By designing the flow path and optics with a completely new approach, this detector is the first significant breakthrough in light scattering detection in decades. Analytical scientists truly benefit from the instrument's unmatched sensitivity and extended capabilities for smaller molecules.

How has COVID-19 impacted your ability to innovate in 2020?
With worldwide restrictions on travels and in-person meetings, as well as universities and labs shut down, innovation in analytical science has been inevitably affected for international companies like Tosoh Bioscience. However, new modes of interactions between our global teams and with our partners have allowed us to maintain our research and development activities. Being creative and out-of-the-box thinking is key to overcome the limitations we face.

To learn more, please visit:
https://www.separations.eu.tosohbioscience.com/solutions/detectors/lens3-detector

THIS MALS DETECTOR LOVES DETAILS

Green light in multi-angle light scattering for highly sensitive measurement of molecular weight and size in GPC, HPLC, and UHPLC

Do you need to determine the properties of polymers or investigate proteins and their aggregates in their native conformations? The LenS3 Multi-Angle Light Scattering (MALS) detector is the first in history to facilitate direct measurement of molecules down to 2 nm in size (the radius of gyration).

This MALS detector, which combines the advantages of low-angle (LALS), high-angle (HALS) and right-angle scattering of light (RALS), exerts its full range of capabilities in polymer and protein analytics. It achieves a high signal intensity by using a green laser and an extended light path. At the same time, the flow cell's construction eliminates noise from stray light and thus ensures high S/N – even with low-concentration solutions. The patented design enables a new calculation methodology of size without complex extrapolation procedure.

The direct measurement of molecular weight and molecular radius for synthetic polymers, polysaccharides, proteins, and other biopolymers is thus simplified.

TED-GC/MS SYSTEM FOR MICROPLASTICS

Thermal Extraction and Desorption (TED)-GC/MS combines large sample pyrolysis with Thermal Desorption (TD) and GC/MS for accurate microplastic analysis

Automated pyrolysis is performed in a thermogravimetric analyzer (TGA), and volatile polymer decomposition products are concentrated by solid-phase extraction in a reusable trap. The trap is subsequently transferred to the thermal desorber for TD-GC/MS determination. The TGA and TD-GC/MS processes are effectively decoupled, preventing non-volatile pyrolysis residues from reaching and contaminating the GC/MS. Automated, uninterrupted TED-GC/MS analysis of large sample batches can be performed.

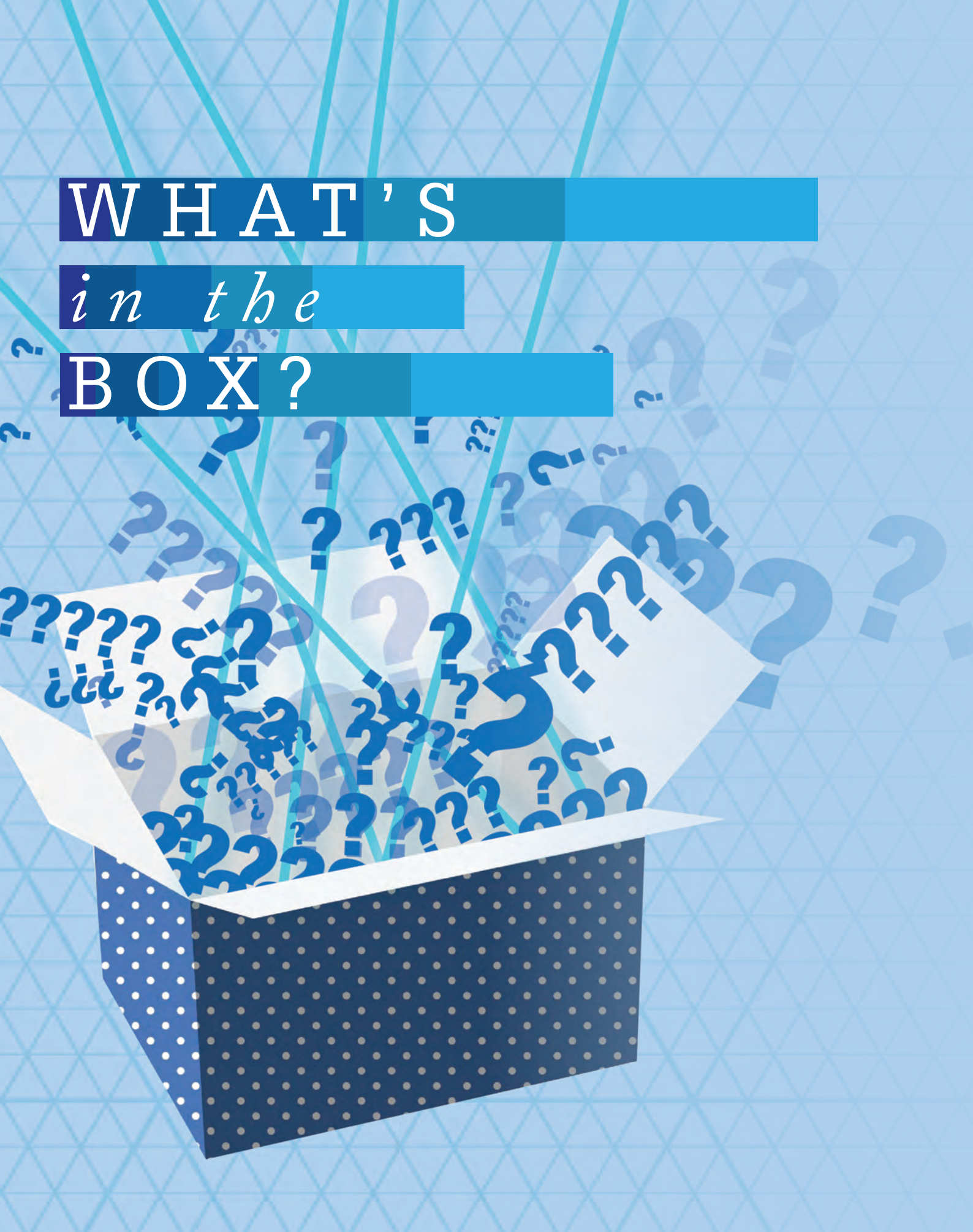
Sample sizes up to 100 mg enable representative sampling and simplify handling - even of soil, silt or compost samples, which only need to be dried and homogenized before analysis. In combination with fractionated filtration, size fractions in air and water samples, including road run-off and drinking water, are easily determined without further sample preparation.

Polymers are determined via specific pyrolysis marker compounds. Identification is comprehensive and verifiable, and quantification can be performed using internal or external standards. Combining large sample capacity, pyrolysis residue elimination, solid phase concentration and TD-GC/MS results in significantly improved limits of quantitation for polymers in complex environmental samples. The GERSTEL ChromIdent Pyro-Edition software enables simple and efficient data processing, even for complex mixtures and matrices. As an added benefit, the TGA curve allows monitoring of replicate sample homogeneity for QC purposes.

TED-GC/MS was invented at the Bundesanstalt für Materialforschung und-prüfung (BAM) in Berlin. The BAM is the leading scientific and technical federal German institute for materials research and testing. Their partnership with GERSTEL led to the development of an integrated and patented interface, and the automated analysis system. An ISO standard based on TED-GC/MS and pyrolysis-GC/MS is under development in ISO TC61 (Plastics) for general ways to determine microplastics.

Find out more: www.gerstel.com/en/TED-GCMS.htm

WHAT'S *in the* BOX?



The roller coaster origin story of the world's first laser ablation, laser ionization time of flight mass spectrometer (LALI-TOF-MS)

By Jeffrey Williams, CEO, Exum Instruments

February 29, 2020 (11 days before the WHO's formal declaration of a pandemic), McCormick Place Convention Center, Chicago

After additional soldering, last minute UI programming, and general wrangling on an Airbnb kitchen table until 3am the night before, we rolled into the Pittcon exhibition hall with the functional insides of something wonderful. We were left with just one seemingly small task to perform: securing the stunning but somehow ill-fitting housing. Neither firm pressure nor brute force (a hammer was involved) resolved the issue. We had been working 18-hour days for 45 days straight, tackling all manner of serious challenges along the way; we would not be foiled by this final hurdle. We erected a makeshift barrier to hide our quickly hatching plan – and then started cutting away at the metal chassis of the instrument with a Dremel [other rotary tools are available]. The high-pitched squealing – and possibly sparks – undoubtedly raised eyebrows...

At 8am, prior to Pittcon opening, we all breathed a sigh of relief. The booth was spotless, our shiny innovation was on display. "That just happened," I sighed. Exum's Massbox – the world's first commercial laser ablation laser ionization time of flight mass spectrometer (LALI-TOF-MS) instrument – was out in the wild.

BORN OUT *of frustration*

My time at the MagLab and grad school (see "The Man in the Machine" for the long version) provided me with the opportunity to work with many different instruments – including every MS system you can think of. And they all had one thing in common – a bad user experience. I think my friend (and now head of applications at Exum) John Putman said it best: "I'm no longer intimidated by the hardware – but, man alive, the software! One wrong click of a button and I can put this million-dollar machine out of commission for months…" I felt the same way. I was also frustrated by how difficult it was to quantify a sample; not only do you have to be a good analytical chemist to get the right data (find a good signal, turn the right knobs in the right order, stand on one foot, do a spin, finally get the peak you wanted…), but you also have to be a master mathematician to make the raw data mean something. The data processing often seems archaic – made all the more obvious when you pull out of your pocket what seems like a supercomputer in comparison. Why does MS so often feel like a 1980s or '90s experience compared with our smartphones? Well, one answer (other than instrument companies typically not having the budget of Google or Apple) is that the instruments are often built on 1980s or '90s foundations. It's a "tech debt" issue; virtual machines running on top of more virtual machines to enable the software to talk to an FPGA chip that was programmed in 1991… In other words, without starting from scratch, redesigning (or simplifying) the user experience is complex.

SCIENCE SIMPLIFIED; *(easy) life on Mars*

The whole ethos of Exum is driven by my desire for a completely different user experience, both from a hardware and software perspective. I think of our efforts as "hardware enabled software" – and that's quite a different design and development philosophy compared with the big players. We must start with robust/stable technology under the hood, so the software can do its predefined job. I was aiming for a "just press go" or "science simplified" experience. It made complete sense to me to develop something that automatically performs the computational tasks I used to do manually – especially when I realized that, in the world of algorithms, we're in a pretty easy-to-solve space. Of course, few analytical chemists like a "black box," so if you want to dive into the details, you can.

The laser system we had started developing in our heads appeared to offer the prerequisite robustness – or linearity – to enable smarter software. In theory, we realized we could sidestep the complexity (and potential failure points) that would take us away from the "clean" software of my dreams. I guess the magic of the Massbox perhaps stems from the freedom to start with a fresh concept – where hardware and aspirational software could be considered simultaneously – one determining the needs and leaning on the strengths of the other.

But how did we arrive at our hardware innovation – LALI? Well, frustration got the better of me again. I needed to know the chlorine and iron content on Mars for my thesis, and the data from the Curiosity Rover was not making life easy. They'd basically sent an uncalibrated instrument up there without thinking about the need to quantify at a later stage.

Over a couple of beers with friends, we started discussing how we would design "a better instrument for Mars 2020." It had to be laser-based MS, and so we started listing all the problems with

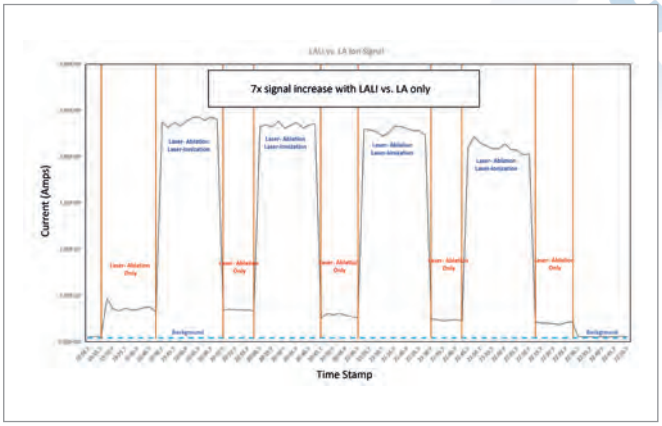


Figure 1. The first raw data! Contrasting signals obtained with laser ablation laser ionization versus laser ablation alone.

LIBS and LIMS, dug into the literature and began to understand how neutral particles fit into the picture (see "Meet the Massbox" for more details). Our first concept was based on tunable-laser resonance ionization, but that got way too complicated way too quickly. Back to the brainstorming. I decided to discuss the concept with Munir Humayun at the MagLab, who asked, "Why not try a second laser?" I did another deep dive into the literature and got excited. We had a novel idea with real promise – and it seemed like a good PhD thesis. Given NASA's passion to find life on Mars, I figured that we should aim target organics and inorganics – so the ablation laser must work in both infrared and UV. As we thought about the potential, we borrowed ideas from here and there, gradually building Frankenstein's concept.

BECOMING FRANKENSTEIN: *escape from academia*

Over time, I was also coming to a realization: I like experimenting and building things. But I hate writing and I hate politics. I was not cut out for the clawing, crawling journey to the top (I had plenty of that when rock climbing). I'd read a few books about entrepreneurship – and it really appealed to me. And I also saw a clear gap and a real opportunity. I figured it was the right idea and it seemed like the right time; my girlfriend was open to the almost certain lack of income that would come with the territory.

So I went for it and quit my PhD (settling for a Masters). Then, the scouring of government auctions commenced; the co-founders and I picked up all sorts of vacuum parts and boxes of fittings and flanges for a couple hundred dollars when they should have cost us tens of thousands. We also emailed everyone we knew in every lab we could think of: "Do you have a turbo pump laying around?" ... "Do you have a spare laser?" I can't go into too many details, but we received some exceptional donations (and there are some pretty expensive empty boxes, complete with barcodes, in certain storerooms around the US).

Eventually, we cobbled together our Frankenstein's monster with acquired parts in my garage. And it did not work. At all. As much as we knew about instrumentation, we had a great deal more to learn. We went back to the drawing board and acquired yet more parts (a challenge with zero money in our bank accounts). At the same time, we started discussions with investors – "We have this great new technology that works…" And we reached out to TOF-MS manufacturers (we knew that a triple quadrupole wouldn't cut it because we needed the whole spectrum from every laser shot). Tofwerk caught our eye – and we caught theirs (at least with "the theory").

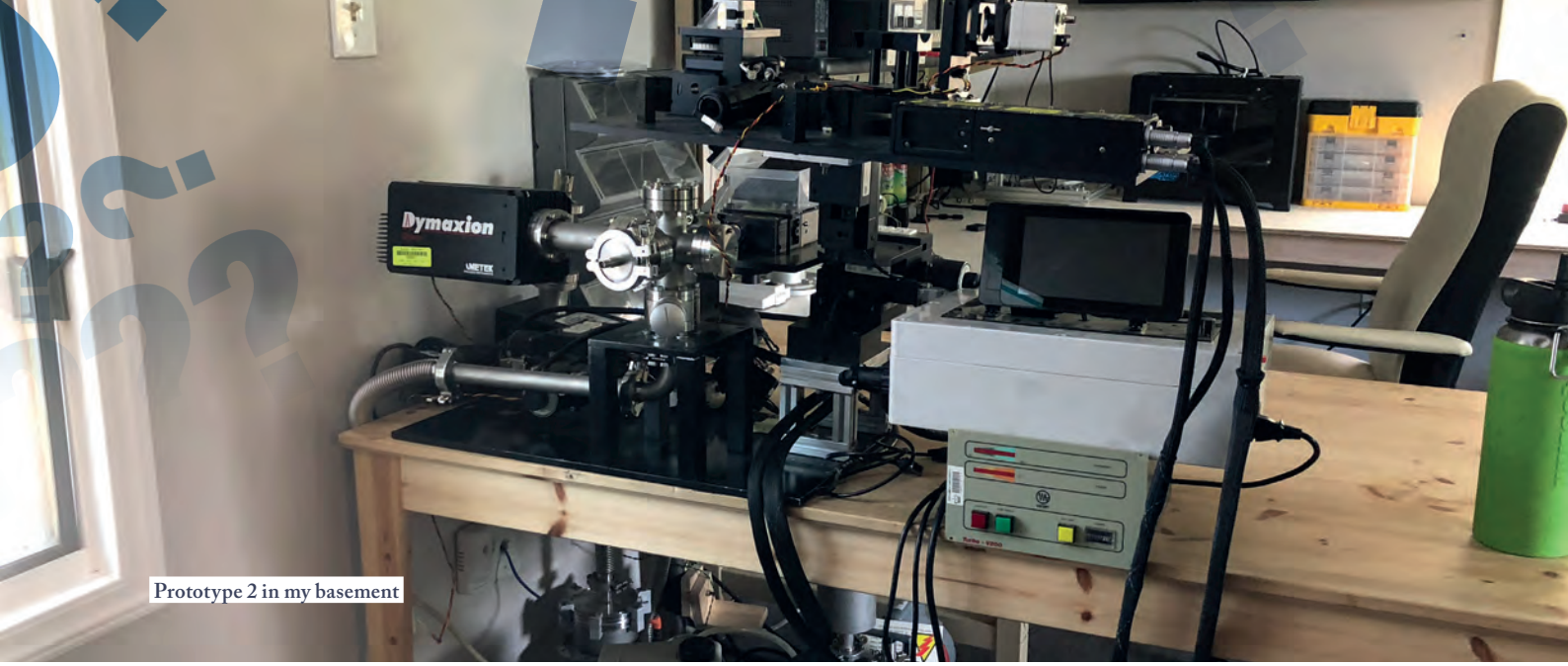
We finally cobbled together the second prototype, which we couldn't find the courage to test; we couldn't take a second huge disappointment. But we could only take potential investors and partners so far on promises – "Show us the data!" It was crunch time; we had a big meeting scheduled with Tofwerk on a Thursday, so on Wednesday night we decided that we needed to bite the bullet – we simply had to align the lasers (and the planets), turn it on, and see what happens… And for the first (and only!) time in Exum Instruments' history, everything worked right off the bat. We saw a massive spike of ions to prove how efficient the LALI system was – and we obtained data for a single figure (see Figure 1).

That single captured moment changed everything. We had proof of our promise. Tofwerk were impressed and jumped on board. The investors were impressed that we'd hooked Tofwerk with our system's technical merits, so they jumped in. As did a laser manufacturer…

ONE GIANT LEAP – *ambitious steps ahead*

We had graduated from my garage to my basement. We had just enough money to keep ourselves alive and plan the next prototype, which Tofwerks agreed to design and manufacture for us in Switzerland. I joined the team there for a month to help put the new instrument together, and then brought it back home. Suddenly, we were pumping out real data – and demonstrating detection limits down to parts per billion; we were competing with an LA-ICP-MS on our second (working) attempt. The investors believed we had a viable product and wanted to push forward. Despite Oleg Maltsev (see sidebar: Ode to Oleg), Steve Strickland (now CFO), and I wearing multiple hats to drive the business forward, it was time to bring in some fresh talent (two mechanical engineers for starters) – especially given the task ahead.

We had the ultimatum of a lifetime. We wanted to transition from our Swiss-made prototype (September 2019) to a full product launch at Pittcon in Chicago (March 2020).



Prototype 2 in my basement

MEET *the Massbox*

The Massbox is a laser ablation laser ionization time of flight mass spectrometer (LALI-TOF-MS) that can be used to analyze any solid material. Your sample could be a rock, a pharmaceutical pill, a cannabis sample, or an apple – if it's a solid or pseudo-solid, the Massbox can determine both the inorganic and organic compounds. Notably, the dynamic range is such that we can determine both the major elements but also the trace elements down to concentrations of parts per billion (see Figure 2).

Let's use a rock as an example (because rocks are close to my heart). You place your rock (sample) into the Massbox, which first takes an image. The image of the rock is presented on the touchscreen, where you are able to select either individual sample spots or run a full map of the whole sample. For every spot, the first laser hits the sample and ablates material to form an initial plasma of excited ions – so far, this will be familiar to users of laser induced breakdown spectroscopy (LIBS) or laser ionization MS (LIMS) – but we don't care about these initial ions; we're interested in the neutral particles that are now floating above the sample surface (like a miniature version of the dust cloud that would result from hitting the rock with a hammer...). With exact timing, the Massbox hits those neutral particles with a second laser, which allows for more "normalizable" ionization of the sample.

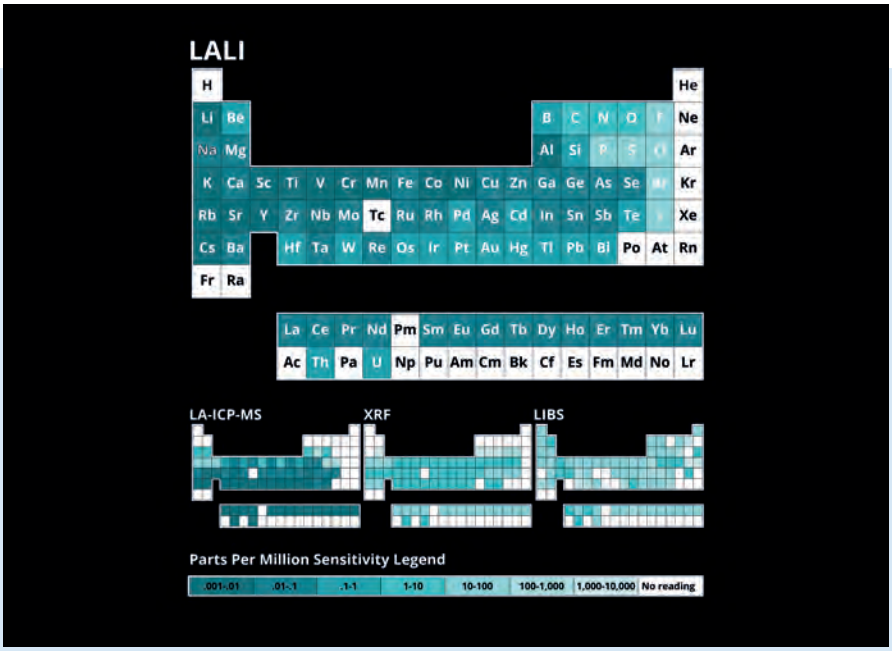
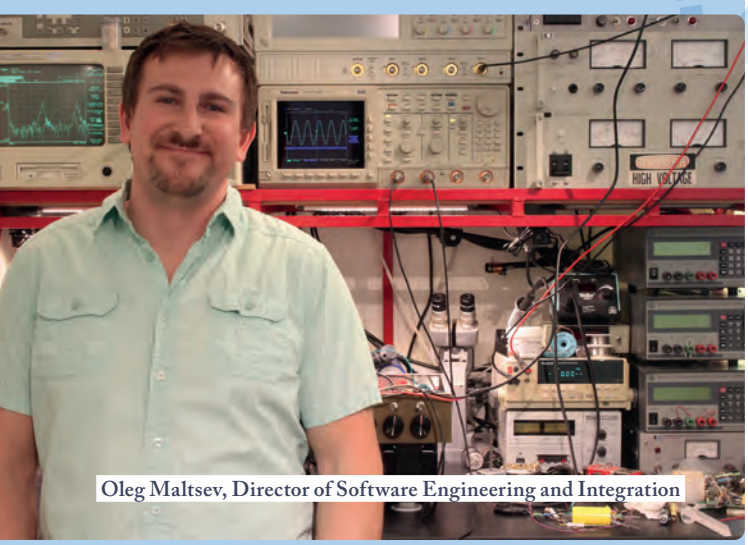


Figure 2. Coverage and sensitivity of LALI-TOF-MS. Comparing element coverage and sensitivity of LALI-TOF-MS versus LA-ICP-MS, XRF and LIBS, visualized using the periodic table.

What do I mean by more normalizable? The ions formed in the initial plasma – as used in LIBS or LIMS – are matrix or chemically dependent; ionization favors those ions that are more easily formed – potassium or sodium, for example – rather than those that are more difficult to ionize, such as silica. In other words, the ratio of elements in the sample is not reflected by the ratio of ions in the resulting plasma, which makes quantification complex at best. But the neutral particle cloud generation is much less chemically dependent, which means that the ions generated by the second laser are much less prone to matrix effects when the laser reaches a "saturation" of energy in the cloud.

Finally, the particle cloud ions are analyzed by TOF-MS in the same way that many MS users will be familiar with.

Perhaps most surprisingly, all of these laser blasts, microexplosions, particle clouds, and MS analyses occur in a desktop-sized, self-contained instrument. Please feel free to check out our website for an animation on how the Massbox works: www.exuminstruments.com



Oleg Maltsev, Director of Software Engineering and Integration

ODE *to Oleg*

Oleg Maltsev – one of Exum's cofounders – is amazing. He can do it all. Anything you can think of, Oleg has done – perfectly. From hi-fi stereos to exceptional carpentry to crazy electronic gadgets, his garage is full of interesting, ongoing projects. In fact, Oleg designed our entire electronics system from scratch (he had experience making tube systems for guitar amplifiers, so understood signal processing and figured he could turn his hand to it!) Today, Oleg is our director of software engineering and integration (having taught himself programming…). He is a true renaissance man. Thank you, Oleg!

Anyone working in the instrument manufacturing business will understand the level of ambition/stupidity. We laid everything out on a Gantt chart; it was technically possible – if everything went perfectly. Nothing went perfectly. One example: we had been quoted an eight-week lead time on the sample stage we needed from Germany; however, when placing the order the lead time had jumped up to 18-weeks – to a date after Pittcon. I begged, pleaded, and compromised to confirm delivery in 16 weeks – the day of Pittcon. We ended up shipping the stages directly to the exhibition floor… Other examples: exploding power supplies, partner delays, last-minute sample chamber modifications…

If you attended Pittcon, you may know that we achieved our goal. We went from another Frankenstein-esque prototype to a beautiful (if I may say so) product, complete with touch screen interface and software platform, in an incredibly short timeframe. I can't say how proud I am of the team. Right up to Pittcon, we had all been working insane hours for months – driven by our belief that it was possible. Looking back, it was a really cool experience. I hope we never have to do it again! I want to say a special thank you to Lacy, Steve, Oleg, Cole, Gurpreet, and Jon for the stupid amount of work you all did to make it happen. Exum would not be where it is today if it weren't for your crazy work, creativity, and ability to have fun at the same time.

FROM PITTCON *to pandemic*

We pulled out all the stops to get to Pittcon with a fully functional instrument (admittedly with last minute Dremel and double-side tape modifications). But that deadline took on a whole new meaning as the true nature of COVID-19 began to play out. As the world transitioned into lockdown, we were so grateful for the momentum we had been able to generate in Chicago. Little did we know then that there wouldn't be another opportunity for a live, in-the-flesh launch for many months (even Pittcon 2021 will be virtual, if you haven't heard the news).

On the exhibition floor, we were amazed by the responses and reactions we received – and the whole Exum team was there to enjoy the moment. It was really fun to watch the dawn of realization on people's faces: "Wait – what? That's a TOF mass spec – and it does solid samples?!" Instrument manufacturers tend to display their systems on cabinets to hide the ugly stuff – additional power supplies, roughing pumps, solvent reservoirs. We had our instrument on a table and people kept asking, "So, what's under the table?"

"Nothing!" we'd exclaim with a sort of magicians reveal, while noting the single power cord. Visitors marveled at how compact it was and how intuitive the integrated touch screen felt. And then we'd show them the super clean mass spectra – and they would be blown away.

We wanted the Massbox to feel like a revolution. And so the genuine surprise – sometimes even confusion about how we achieved so much in such a small box – felt like a real validation of the original concept. And because we had the chance to chat with scientists from all sorts of backgrounds, we were suddenly looking at a whole host of application areas that hadn't even crossed our minds. The future looked filled with potential and opportunities. It felt like a celebration.

Then COVID-19 hit with full force. And we felt so grateful to have worked so hard to hit the Pittcon deadline. We had already established Exum Instruments as a company and introduced the Massbox. As the pace of life slowed, we had ample time to follow up on conversations and leads from early March. And the interest generated at Pittcon inspired us to set up a virtual lab, where we can run people's samples live on the instrument and send the data directly to their inbox. Over the intervening months, we've got into all sorts of interesting application development directions –

Prototype 3 – made in Switzerland

Jeff Williams, CEO

MEET THE MAN *in the Machine*

I was not the world's best school kid – I did just enough to get by. I wasn't scientifically or mathematically driven. Rather, I was the rebellious skater/artsy kid at the all-boys catholic school. Almost inevitably, I became a graphic design and studio art major (a long way from mass spectrometry). I also got seriously into rock climbing and, at some point on an ascent, had an epiphany: "Wow. Rocks are really cool!" Why is granite different to limestone? What are all these layers? For fun, I took a crash course in planet science and was fortunate to have an amazing professor who got me even more excited about rocks. Suddenly, I wanted to become a geologist. I also realized I enjoyed – and had an affinity for – chemistry through some introductory courses and yet another amazing professor at community college. (Sidenote: I'd like to give a big shout out to community colleges. They get such a bad rap, but they were home to some of my best teachers). I loved geology and a loved chemistry – and I wondered if there was a way to marry the two. Is geochemistry a thing?

A few twists of fate later, and I found myself on a tour of the MagLab (the National High Field Magnetic Laboratory) in Tallahassee, Florida with Munir Humayun (still the smartest and most genuinely enthusiastic person I have ever met) and I knew I had to work there. I asked if there were any undergraduate research positions available – "Unfortunately, not." But I wouldn't take no for an answer and offered to work for free. "I'll even do the worst job ever..."

"OK. I've got the worst job ever," said Munir who had been involved with the NASA Genesis mission. When the sample-return probe crash landed, the team salvaged a mixture of paint and precious metals chips. And my first ever chemistry project was to figure out how to dissolve the paint and not the metal. In other words, rather than watching paint dry, I was tasked with watching paint dissolve – for weeks. I believe it was a test of my mental resolve.

I passed the test and finally got into some real projects – laser ablation, meteorites… And I realized I'd fallen in love again: cosmochemistry. After perhaps the most productive year of my life at the MagLab, I headed off to grad at the University of New Mexico (studying under Zachary Sharp), where I moved onto tracking elements to unravel the mysteries of early solar system formation. I even got to work on Curiosity Rover data. I also used a whole bunch of cutting-edge instruments – but, despite their supposed advanced nature, I started thinking: "There must be an easier way."

several sparked by those initial Pittcon discussions.

Prior to our Pittcon launch – and very fortunately for us – we had already been doing some soul searching about target markets and application areas. Initially, we were really focused on the energy sector – oil and gas specifically. But we were getting a lot of early interest from other industries and we had started to question our initial assumptions: was oil and gas really the best fit? Post Pittcon, mid pandemic – and as oil slid into negative value in the States – we were pleased that we had broadened our analytical scope for Pittcon! The pharmaceutical industry is one exciting avenue – as is the rapidly emerging world of cannabis testing, where we can bring speed and simplicity to trace metal analysis. Metallurgy and material science is another good fit for the low limits of detection and high precision of our technology; scientists may want to characterize a special indium alloy on a manufacturing line, for example.

COVID-19 made the world a different place (and "normal" is still some way off). Despite the clear downsides of living with a pandemic, people seem to have been a little more open to alternative approaches and innovation. We've been given an unusual opportunity to interact with potential users while they've had a little more time to stop and think about cool, new technology and smarter routes to the analytical data they need.

Meanwhile, we've also had the time to tweak and perfect the instrument (sticky tape and rotary tools no longer required).

We have actually completely redesigned the instrument two more times since the version at Pittcon. It's now very much production ready and continues to surprise us with its capabilities, and so we've had some amazing experiences doing digital demos with customers. In fact, as of writing, we've now sold two instruments – just seven months after the initial launch of the prototype (and in a pandemic). We also received a $250,000 grant from the state of Colorado. In all honesty, there is too much excitement to fit into a single article; maybe I'll write part II in a couple of years to get you up to speed… We know that we still have a long way to go to become the full vision of Exum, but we are eager and determined to face the challenges ahead.

Solutions

Real analytical problems
Collaborative expertise
Novel applications

Better Methods for Better Vaccines

When it comes to virus and viral protein analysis, settling for "gold-standard methods" isn't good enough. To navigate the roadblocks ahead of successful vaccine development, we must dig deep into the analytical armamentarium

By Ewoud van Tricht, Senior Scientist, Analytical Development, Janssen Vaccines and Prevention, Leiden, the Netherlands

Since Jenner first inoculated a young volunteer with his magic cure for smallpox in 1797, the power of vaccination in preventing infection and eradicating infectious diseases has surely been realized. This year, the spotlight has once again turned towards vaccines, as both scientists and the general public cling to somewhat remote hopes of a return to "normal." Before now, the fastest we have ever managed to produce a vaccine in response to an outbreak was for Ebola – and that took five years to achieve full licensure. The rulebook may have been ripped up, but it is perhaps now more vital than ever that the entire vaccine development process is as efficient, precise, and cost-effective as possible. Developing the right analytical methods using the best tools for the job has an absolutely key role to play.

An insight into adenovirus vector development

Ordinarily, our work at Janssen Vaccines and Prevention – a pharmaceutical company of Johnson and Johnson – is focused on the research and development of vaccine products against infectious diseases like Ebola, HIV, and RSV. So it should come as no surprise that our attention has turned to COVID-19 this past year. Typically, we look at developing modified adenoviruses for intracellular delivery of DNA. Our Advac® technology allows the production of adenovirus vectors in which the viral DNA can be modified to encode an immunogen of interest. In the case of our Ebola vaccine, this is a particular viral glycoprotein - upon vaccination, a protective host immune response against the virus is achieved.

The same Advac® technology has been used across our COVID-19, Zika, RSV, and HIV vaccine candidates. Overall, more than 100,000 people have been immunized with vaccines based on Advac® technology, which demonstrates the safety of our platform. Such technology platforms make it possible to quickly develop new candidate vaccines and then produce the optimal ones on a larger scale. Our Zika, RSV, and HIV vaccines are currently in phase 2 or phase 3 clinical trials. On July 22, the first healthy volunteer was injected with our COVID-19 candidate vaccine; interim results from the phase 1/2a clinical study showed that the safety profile and immunogenicity after a single vaccination were supportive of further development. In September, the first patient was dosed in a phase 3 clinical trial to evaluate safety and efficacy of the vaccine in up to 60,000 adults worldwide. In addition to this single-dose regimen ENSEMBLE study, as of November, Janssen initiated a two-dose regimen ENSEMBLE 2 trial which will study the safety and efficacy of the vaccine in a further 30,000 participants . Though we are accelerating vaccine development at the moment, safety and efficacy are never compromised.

My work within the analytical assays (AA) group has been to improve the methods used for analysis of viruses and viral proteins throughout the entire vaccine production process. Our aim was to extend the analytical toolbox for the characterization of vaccine products, helping to overcome the challenges associated with traditional methods. Not only have we developed three new analytical techniques for vaccine development in recent years, we have also implemented a systematic analytical quality by design (AQbD) approach to ensure the right method is developed for the right purpose.

The true value of analysis

The focus of our AA group is on developing, validating, and transferring methods for

different groups within the organization – namely, Process Development, Formulation Development, Product Characterization and the Production Plant. Each department can request method development, validation, and transfer through an analytical target profile (ATP). The purpose of the ATP is to give clear direction to the AA group – it should capture the purpose of the test method, the method requirements, and the reportable results. Importantly, it is defined upfront and agreed between the method developer and the person who requested it.

Clearly, the requirements of any analytical method depend on what it will be used for. For example, quality control methods must be validated, straightforward, robust and reliable. On the other hand, the typical requirements for a process optimization method are a rapid time to result (so as not to delay the production process) and large sample throughput.

We develop analytical methods for a diverse set of purposes:

- Release of material for clinical use – to assure safety and quality of the product
- Stability studies – to assure quality of the product throughout its lifecycle
- Product knowledge – for in-depth characterization
- Process optimization – for example, yield or formulation

After a method has been developed, we then look at its transfer and validation. Analytical methods routinely used for release of clinical material or stability studies will be transferred to the quality control laboratory, which operates under good manufacturing practices (GMP) regulations with validated analytical methods. The methods routinely used for process optimization are transferred to the Biophysics and Process Analytics group, which analyzes up to 30,000 samples per year and is specialized in supporting process and formulation development.

Complex and new analytical methods – or methods that are only used for a single study – are not transferred. In these cases, analysis is performed within our own AA group by those who developed the methods.

A path fraught with difficulty

The nature of viruses throws up a number of hurdles that must be navigated by analytical method development teams. First of all, the instability of viruses outside the host environment makes it particularly difficult to select the right technology for the quantification of viruses or viral proteins. Viruses are best adapted to surviving and efficiently replicating in the ideal host environment. Outside the host, however, viruses are more easily affected by pH, salt, and temperature changes, which can cause degradation or aggregation. Many technologies require a complex sample treatment to infect cells, to achieve antibody-antigen complexes, to reduce viruses into proteins, or to provide cleanup of the complex sample matrix of viral products (like a vaccine). In addition, many analytical methods require separation conditions – such as organic solvents, surfactants, ion pairing agents or silica-based stationary phases – which may be unfavorable for viruses.

Secondly, the adsorption of viruses and viral proteins can pose a serious challenge; viruses and proteins tend to adsorb to sample vials and instrument parts, such as the injector, valves, tubing, columns, and capillaries.

Finally, the matrix of the crude viral product is typically highly complex and could contain host cell DNA, proteins, cell debris, salts, and surfactants in different ratios and amounts. There is a distinct challenge in separating the virus from these matrix components and preventing their interference with the analytical measurements.

All of these challenges must be carefully considered in analytical method development to ensure successful analysis of viruses and viral proteins.

A three-pronged attack

To overcome the issues typically observed with traditional methods, such as low throughput, limited sensitivity, and matrix incompatibility, our AA team developed three new analytical methods – all previously published – for the analysis of viruses and viral proteins throughout the vaccine production process.

Meet Ewoud

An analytical chemist with over 14 years' experience in the pharmaceutical industry, Ewoud started working for Solvay Pharmaceuticals in 2006 after finishing his MBO (middle-level applied education – the equivalent of junior college education in the US), but quickly realized he needed at least a Bachelor's to pursue his dream of becoming an analytical method developer. He decided to take on part-time study alongside his fulltime job, and between 2006 and 2020 he has completed a Bachelor's, Master's, and PhD in analytical chemistry while working for both Abbott Healthcare (2006-2010) and Janssen Vaccines and Prevention (2011-2020).

During this time, he's held many different positions across a broad range of departments. He started working at Janssen Vaccines and Prevention (previously Crucell) as a senior technician in Quality Control back in 2011. Now, he is a senior scientist in the AA department. AA is a group of 25 people within the wider Analytical Development department responsible for the development, validation, and transfer of analytical methods for the analysis of vaccines products. The focus of this group is on developing analytical methods with separation technologies (capillary electrophoresis, LC, MS) and physical characterization technologies (field flow fractionation, analytical ultracentrifugation). Not only do they analyze the main component of vaccine products – typically a virus or a protein – but also the additives and impurities respectively created during the production process or added to the final formulation.

For the last few years Ewoud has been focusing on statistical analysis, dossier writing, and analytical quality by design (AQbD).

The first is a capillary gel electrophoresis (CGE) method for the quantification of influenza virus proteins and virosomes (virus-like particles) (1). In comparison to single radial immunodiffusion (SRID), RP-HPLC, and SDS-PAGE, the CGE method confers some key advantages. Using the CGE method, we found it was possible to determine three other major proteins in addition to the main influenza protein: HA fragment 2, matrix protein, and nuclear protein. Although CGE could reproducibly separate all four major proteins, quantification was not possible because of the lack of (commercial) reference standards. However, the fingerprint of the CGE electropherogram of the four proteins was specific and could be used to identify the virus strain. The precision and accuracy of CGE was similar to SRID, but the total analysis time for the CGE method was much shorter, allowing analysis of 100 samples in four days instead of ten days for SRID.

The second method we developed uses RP-UHPLC-UV for quantitative adenovirus protein profiling (2). Using our method, all adenovirus proteins could be baseline separated within 17 minutes on a C4 column (300 Å, 1.7 µm, 2.1 x 150 mm) with a water-acetonitrile gradient containing 0.175 percent w/v TFA as the ion-pairing agent. The adenovirus test samples were directly injected into the UHPLC system without the need for sample pre-treatment and the viruses dissociated into the viral proteins upon contact with the acetonitrile/water mobile phase. Our RP-UHPLC-UV method was successfully validated for two purposes: confirmation of the identity of the test sample and detection of protein modifications or degradation products of the adenovirus vector. The method can detect changes in the adenovirus protein composition as a result of thermal or oxidative stress, as well as impurities, such as protein degradants, leachables, and host cell proteins. For RP-UHPLC-UV, the sample throughput was increased by a factor of 6 by reducing the run time from 130 min to 17 min. With the improved run time, up to 50 samples could be run in a single sequence without impacting sample stability.

Thirdly, we also developed a patented (3) capillary zone electrophoresis (CZE) method for precise and accurate analysis of adenovirus samples containing variable amounts of cell debris, cell lysate, host cell proteins, host cell DNA, salts, detergents, and additives (4,5). The CZE method offers an alternative that circumvents issues with current methods – qPCR and anion exchange (AE)-HPLC. Intact adenoviruses from upstream (USP) and downstream processing DSP can be directly

analyzed by CZE and only samples with high amounts of host cell DNA require a simple benzonase sample pre-treatment. The CZE method has been validated for the quantification of adenovirus throughout the production process. A great advantage of CZE is its compatibility with USP and DSP samples – and their variable matrices. In contrast, AE-HPLC is only suitable for purified adenovirus samples. And with a run time of only 3 min, CZE allows the analysis of 30 samples within 4 hours compared with 3 days by qPCR! Precision and accuracy is also significantly improved compared with AE-HPLC and qPCR. In particular, the improved precision of the CZE method makes it possible to improve the formulation or production process, as smaller process improvements can be detected with adequate statistical confidence.

How we got there: analytical quality by design

As part of a continuous improvement project alongside this work, we mapped the process of method development in detail based on input from scientists (6,7). We learned that the complexity of the process and a lack of standardization can result in long lead times for method development and lack of robustness in resulting methods. In short, redevelopment and troubleshooting were too common.

Additionally, for many of the methods the purpose was not clearly defined upfront and that led to improper use or implementation. Analytical method development was typically technology/method-driven rather than product/analyte-driven; methods were often selected because the technique was commonly used, in-house experience was available, or the technique was "at hand." An assessment to verify whether the selected method is indeed the best choice for the specific product and analyte was mostly lacking. Finally – and especially for complex vaccine products – the matrix and the analyte did not typically match up with the analytical method conditions used.

Put another way, concessions were being made in favor of the analytical technique, but were not optimal for the tested product. The final developed method only produced the "best result" that could be obtained within the restrictions of the analytical method rather than the best result from a given sample. As a result, complex and extensive sample treatments were introduced, and a compromise of suboptimal conditions were being selected.

Based on this information, we decided to implement an analytical quality by design (AQbD) approach when it came to the method development outlined earlier. AQbD consists of six defined steps:

- Definition of the analytical target profile (ATP) describing the objective of the test and the requirements
- Technology selection
- Definition of the critical method parameters by a criticality (risk) assessment
- Method development by design of experiments (DOE)
- Method validation and control strategy
- Method maintenance or method life cycle management

The first challenge we encountered was the lack of guidelines describing the application of AQbD in practice. Typically, only the vision, rationale and a high-level approach to AQbD are described in the literature, meaning tailor-made tools had to be created and developed for most of the AQbD steps. We have now successfully developed and implemented tools for each of the AQbD steps, and we have created training material and courses for scientists in analytical development.

The AQbD process overcomes the issues associated with a lack of standardization. AQbD offers a structured, risk-based approach for method development. The knowledge and decisions made are captured and can be shared and reused. As a result, training of new operators is more focused and there are fewer invalid analyses when the method is applied to real samples.

After all steps of AQbD were applied, and a comparison of six analytical methodologies was carried out, CZE was selected as the method of choice for adenovirus analysis.

Change is never easy, but it is possible: a CZE success story

Despite the clear advantages, it took years for our CZE method to be implemented within the organization. In particular, we had to overcome prejudice with regards to the robustness of capillary electrophoresis instruments and a general belief that CE could never be run in a QC environment. We sent our colleagues to theoretical CE training to get the background knowledge they needed and our team gave over 50 presentations about the possibilities and versatility of CE. At last, we convinced them (with the data to back it up) that CZE could indeed compete with the current technologies.

Two years after finishing the method development, CZE was to be qualified in a QCD laboratory for their in-process control test of virus particle concentration during the production process. The virus concentration could be reported within 2 hours – it had taken 1 to 3 days with the previous techniques. An extensive system suitability test and trending of critical data from the analytical method assured them that, after 525 analytical runs (over two years), the precision and bias of the method still adhered to the original requirements from the analytical target profile. Continuous improvement of the CZE test method after implementation and training of the operators proved key to successful daily operation. In 99.4 percent of cases, the sample data could be generated on the same day adhering to ATP requirements. For other techniques, the data was typically reported on the same day in 75 to 95 percent of cases.

Since then, we have bought eight CE instruments, trained over 20 operators, implemented CZE at six locations, run more than 15,000 samples and we now routinely use 3 CZE applications.

What does all this mean for COVID-19?

Further to these benefits, the new analytical technologies we developed have also allowed for quick adaptation and implementation with our new COVID-19 vaccine program. I am the responsible scientist for the Ebola vaccine project, but this year I have also been brought in as the subject matter expert for the CZE method that is used for in-process control testing of our COVID-19 vaccine. I am also the responsible scientist for the method used for aggregation determination for characterization of the vaccine product, and have supported the COVID-19 dossier by reviewing the sections describing our analytical release and stability methods.

Our group had two main analytical activities when COVID-19 was announced as our new candidate-vaccine. The main advantage of many of the analytical methods developed in our team is that they can be used for the accurate and precise determination of any type of adenovirus-associated vaccine, such as COVID-19 or Ebola. Our job was to make sure that all these analytical methods were ready to use before COVID-19 production started – thankfully, our platform methods significantly reduce the amount of development and validation work that is needed for a new project. Once all analytical methods used for the characterization of the vaccine were shown to be suitable for our COVID-19 program, they were successfully used to characterize the vaccine batches currently in clinic.

I am extremely grateful and proud that our AQbD approach has finally offered a standardized approach for method development, validation, and implementation for virus analysis. It's great to know that our organization is now ready for upcoming guidelines (ICH Q14 and USP <1220>) that will recommend using the AQbD approach. Being able to align different development groups and scientists has fast-tracked our vaccine development program – and we've also ensured method development knowledge is captured, reusable, and shareable. Our approach to analysis has not only saved us time and money, it has also provided more information than traditional methods. It has allowed for more efficient production processes, higher quality vaccines, a better understanding of these vaccines, and ultimately made them more affordable.

Please see references online at: http://tas.txp.to/BetterMethodsBetterVaccines

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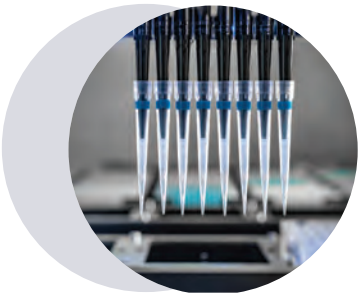

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Sitting Down With…
Andrew Whitley, Vice President of Sales and Business Development, Horiba Scientific, Piscataway, New Jersey, USA

You are a classically trained scientist with a PhD in analytical chemistry, but it was marketing that captured your attention – why?

My PhD at the University of Durham (sponsored by Shell) involved looking at some interesting applications of Raman and infrared spectroscopy to study the viscosity of model lubricants. After I graduated, I didn't want to get stuck on a bench, focusing on one area of research – so I applied for a customer-facing role at Bruker. It was a good fit because it wasn't just regurgitating brochures, as I had feared – Bruker really focused on the science behind their instrumentation. FT-Raman was really starting to take off, so I had an exciting three years. I really enjoyed interacting with people and helping them with their research.

How did you end up in your current role?

After Bruker, I joined Renishaw to help set up their global sales network for Raman microscopes. They then asked me to head up Raman for them in the US in 1995. My job was to grow the business from out of California and into the rest of the States.

In 1999, Horiba A headhunted me for a job in New Jersey and I've been here ever since! I started off as the North American Raman product line manager at the time when dispersive Raman microscopy was starting to take off. FT-Raman had acted as the catalyst for a renewed interest in Raman, but FT-Raman microscopy was not sensitive enough for most applications. Because of the early success of these systems, I later became VP of Sales and, eventually, VP of Sales and Business Development.

What are you most excited about in the field?

We have been working on a new technology called A-TEEM (Absorbance – Transmission Excitation Emission Matrices). It utilizes fluorescence EEM's spectroscopy combined with simultaneous absorbance spectroscopy. You vary the fluorescence excitation frequency, measure the emission at different frequencies, and then use this to get information about the concentration of the different molecules and the molecular environment. Until this technology came along, Raman was my big spectroscopy passion, now I have two!

There are lots of interesting applications as well – for example, cell media applications to help pharmaceutical companies show they have good quality raw materials and the right drug product throughout and at the end of their process. We've even used EEM to forecast the quality of wine from the juice and end product, and predict its performance over a number of years.

How has innovation evolved - and does this differ around the globe?

When I first joined the industry, the approach to innovation was, "If you build it, they will come." Engineers were focused on first improving the instrument, then finding applications for it. Now, it's more like, "This application needs this technology; how can we change our instrumentation to suit market needs?"

In the US and Europe, there's more of a desire (and an established process) to involve multiple industrial companies and universities in the business development process. In Asia, there has been a different approach. Traditionally, innovation is driven by the needs of a big client, which can be risky as it means developing applications or products that might only be relevant to one customer. That's why my passion is focused on the marketing side of things – to ensure we're developing something that meets the broadest need.

What do you like to do outside of work?

I'm a big Nottingham Forest fan, and I often go into New York to watch football. The New York City Supporters club of Nottingham Forest meet in the Smithfield Hall pub to watch the games. There are about 20 of us in the core group, but a lot of people come visit when they are over on vacation because they've heard about us.

If you had a time machine, where would you go?

I love music, especially alternative music, so I'd probably use it to watch some of the greatest concerts. Specifically, I'd love to see Queen perform their Live Aid concert and I'd probably go to Woodstock as well.

What's your advice to people starting out in the field?

I always advise people to take risks when they are young – I don't know if I did that enough when I was younger. I would tell them: be an entrepreneur or work for a startup company when you find something you're passionate about. If you fail, you can always look back and say, "At least I tried" – and that experience will undoubtedly help you later in life.

What are you most proud of?

I'm really proud of my four kids. My oldest son, George, lives in the UK, and I'm extremely proud of him because he's doing what he's passionate about – teaching. Within my work team, I have a very high retention rate. I always hire people I know can be better than I am – you should never be scared of someone overtaking you in a company. I'm proud that people are happy in my team. I have a photo of my early Raman team at Horiba from about 18 years ago and I'm proud to say that every single one of them is still working within the Raman team today.

At Horiba, one of the main philosophies is "Joy and Fun", this means if you're not happy in your role, you should look for another within the company. If you're still not happy, then you should just look for another job. That's unusual for companies in Japan because people tend to stay at one company for life. Even before I joined Horiba, I strongly believed we have a responsibility to our employees, to help and encourage them to enjoy their job. You have to enjoy what you do – it takes up so much of your time that, if you don't enjoy it, what's the point?

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