L@b Brief | October 2022

Hello again,

IT'S SURPRISING, given all the turmoil in the UK, to see the Europeans getting themselves into trouble of their own making for a change. The farrago over the change from the Medical Device Directive to the Medical Device Regulations looks set to have a negative effect on sales of medical devices into the EU with huge hold ups in getting equipment certified in order to meet the requirements of the new regulations.

It's a lawyers' charter of course with manufacturers desperate to keep selling and customers relying on the devices desperate to buy. Only a few limited exemptions in a few territories are available to them and the situation has all the potential to be even worse for IVDs - albeit as a slightly longer term car crash.

At least in the UK we are taking a pragmatic approach and delaying implementation until we can get products through the hoops. (see Medical Device Regulations story below). If there's an action to take as a result of this, it's to find yourself a conformity assessment body now, be nice to them, and never ever let them go!

Toodle pip!
Jacqueline

INSIDE *this* ISSUE

UK News

Ben Goldacre to speak at GAMBICA conference in March 2023

WE ARE thrilled to announce that Ben Goldacre, psychiatrist, physician, academic and author of the notorious 'Bad Science' and 'Bad Pharma' books, will be the after-dinner speaker at the dinner of our Lab Suppliers' Conference in March. Ben is Professor of Evidence-Based Medicine and director of Oxford's Bennett Institute for Applied Data Science. He is also the author of a recent report on how the NHS can optimise its activities by better use of data science.

The conference will be a star-studded event next year as Anand Menon, who recently added Radio 4's *The News Quiz* to *Newsnight* and the many other media slots for which he has provided analysis, is set to contribute his insights on the current international trading scene.

As well as the political and economic reviews to help you with your planning, the conference will focus on getting your key customers into the room to explain what they will be looking for in the coming period.

The conference will also feature the latest expert views on how to refine your go-to-market strategy and what actually works best when selling B2B. The 'Green for Growth' conference will have two major themes; growing sales, and the sustainability 'permit-to-sell'.

The pharma industry is taking to heart its UN Race To Zero targets and has started on lab certification in large numbers. In order to address their Scope 3 emissions (those not under their direct control) most of the major lab customers are now setting sustainability targets for their providers. In a session devoted to the resulting targets you will hear from two major pharma clients, and then find out how GAMBICA can help you can take your first steps to meet their expectations and benchmark your sustainability performance against your peers.

Failing to meet clients' sustainability requirements will be as effective a barrier to trade as failing to meet current legal requirements. The conference will help you to get ahead of less forward-looking companies. We really hope you can join us.

To book your place at early bird rates, click here

MDR and IVDR delayed

IN LATE October, the Department for Health and Social Care (DHSC) announced that there will be a twelve-month extension to the current standstill period on the UK Medical Device

Regulations (MDR), with the Department now aiming to bring the new regulations into force in July 2024.

In a letter to the industry the department says: "We are committed to ensuring that the future regime is robust and reflects the detail required to avoid disruption to supplies, support innovation and enable safe access to Medical Devices for UK patients… For clarity, the timelines for the transitional arrangements will commence from when the new regulations come into force (i.e., July 2024). The MHRA aims to lay legislation in Spring 2023 to bring into force not only the transitional arrangements but also some post-market surveillance requirements."

The letter also acknowledges concerns about capacity across the Approved Body system. In a webinar for GAMBICA members in October, MDR and IVDR partner at Taylor Wessing, Alison Dennis noted that while the situation for getting medical devices certified is a problem in the UK, in Europe it is far, far worse. "85% of devices certified for sale under the Medical Device Directives have not yet been certified under the Medical Device Regulations and most of the time available has elapsed. 30% of SMEs have not even been able to find a notified body to review their applications and those notified bodies which are taking work are so swamped that they appear to be rejecting over half the applications as being 'incomplete', simply as a way of managing their workloads."

While overall it is agreed that medical device manufacturers have been somewhat slow to apply for certification under the new regime, notified bodies are also being slow and unresponsive, particularly to SME applicants. Alison Dennis was of the view that some exemptions from re-certification do seem to be available in some territories within the EU, but in general the European Commission appears to be sticking to its guns and refusing to allow uncertificated products to be sold, even where there is a clear risk to the lives of patients (which can be the case where no equivalent product is available).

There are currently four designated UK Conformity Assessment Bodies, with six more in the pipeline and the DHSC believes that this makes the UK an attractive place to develop and market medical devices.

The British Healthcare Trades Association has asked how the July 2024 re-set will interact with timetables already set for the EU MDR and in particular the currently-applicable regulations that deliver the checks and proofs (labelling, Declarations of Conformity (Class 1 devices), CE Certificates (Class 2-&-above devices)) that DHSC/MHRA will accept until July 2024. In May 2024, Certificates issued under Medical Device Directive (MDD) become void; so this is the last date for placing medical devices on the market unless they meet MDR requirements and as was made clear to GAMBICA members at the recent webinar, many devices will at that point cease to be eligible for CE marks.

Concerns have been raised as to whether the MHRA team responsible for managing the applications for exemptions for medical devices exceptional use will be staffed adequately to match the likely demand.

According to the BHTA ***existing*** customers of UK CABs/EU NBs face waiting times of 12-18 months for completion of audit and compliance tasks (from simple recertification to more complex MDD-to-MDR conversion), and ***new*** customers are being turned away

entirely. Concerns are being voiced that having removed a possible July 2023 cliff-edge, another will re-emerge in July 2024.

Separately, the European Commission Decision Reliance Procedure (ECDRP) has been extended and will continue to be available until 31 December 2023. The ECDRP allows a company to submit a product that has received approval from the European Medicines Agency to the Medicines and Healthcare products Regulatory Agency. More information here.

Rolling blackouts – how should you prepare?

JOHN PETTIGREW, the chief executive of National Grid, highlighted at a conference in October that there are real 'cut off' risks this winter, warning of a significant strain on the UK power grid in the deepest darkest evenings of January and February.

While blackouts are said to be 'unlikely', it is still possible that to manage demand forced implemented blackouts will be required. These will probably come in the form of rolling, three-hour cuts to the power between 4-7pm.

Businesses which allow employees to work from home will need to consider the possibility of internet connectivity problems during blackouts and implement emergency management policies for widespread power outages.

According to Nishma Chudasama, employment solicitor at SA Law: "Before a blackout, employers should carry out risk analyses and take the required steps to provide a safe workplace for their staff," to "lessen the likelihood" of an accident and any ensuing legal action.

Staff may well find themselves having to turn down the heating and while there is no legal requirement to keep a workplace at a minimum temperature, employers should be aware of this possibility. While it may be possible for employers to give notice to staff to use up holiday leave during power outages, the Working Time Regulations 1998, stipulate that the period of notice must be twice the period of the leave to be taken. Employers may wish to consider whether their existing policies for a shortage of work enable them to place staff on short-time working, and reduce pay to time-worked only, during blackout periods. But Alexandra Mizzi, solicitor at Howard Kennedy, notes that if businesses must close, "there may not be a legal right for companies to send employees home without pay" unless they have layoff or short-time working provisions in their contracts or where staff are engaged on zero hour contracts.

Innovate UK updates its medicines manufacturing support

A NEW webpage introducing the next stage of Innovate UK's Medicines Manufacturing Programme is now available. This will build on the previous Medicines Manufacturing Challenge which invested £360 million in developing first-of-a-kind technologies to manufacture medicines and accelerate patient access to new drugs and treatments.

For more information click here.

Economic Crime & Corporate Transparency Bill will mean more checking at Companies House

THE ECONOMIC Crime and Corporate Transparency (ECCT) Bill which is likely to achieve Royal Assent in the spring of 2023 will reform the role of Companies House to improve the transparency of UK companies and other legal entities. Its changes include:

- Introducing identity verification for people who register companies or file with Companies House; this will improve the accuracy of data and support business decisions and law enforcement investigations;
- Broadening Companies House powers so that it becomes a more active gatekeeper over company creation and a source of more reliable data; Companies House will also be given new powers to check, remove or decline information.
- Improving the financial information on the register so that it's more reliable, complete and accurate, reflects the latest advancements in technology, and enables better business decisions.

Companies House will be able to proactively share information with law enforcement bodies where they have evidence of unusual filings or suspicious behaviour.

Government U-turns on IR35 repeal

IN OCTOBER, new chancellor Jeremy Hunt, scrapped plans to abolish the changes to off-payroll working rules announced by his predecessor Kwasi Kwarteng.

As part of its latest reversal of IR35 reforms, the government will no longer repeal the changes to off-payroll rules from 6 April 2023. The volte-face by Hunt means that organisations will remain responsible for determining their workers' status for tax purposes and accounting for any tax liabilities when working with contractors.

Market access and knowledge are key issues for GAMBICA's biotech members

MEMBERS OF GAMBICA with an interest in the biotech industry met recently to input on the services they need to help them optimiSe their businesses. Two strong themes emerged - access and knowledge.

The number of GAMBICA member companies with a direct interest in biotech has been growing rapidly and in order to identify what specific services are most important, expert members in the field met to identify where GAMBICA can best focus its services; and prioritise the issues they want us to tackle, both now and in the future.

That ‘access’ is a major issue became clear right away with the following highlighted as common problems:

- Access to stakeholders (47%)
- Sustainability (20%)
- Technologies (13%) (both technological development in products, and developments in channels)
- Regulations (7%)
- Contracts and purchasing (7%)

The main suggestion for GAMBICA was to provide easy-to-access information on what’s going on in the world of biotech, what’s driving purchasing companies, including regulation and technological developments.

We will be giving some thought as to how best to achieve this and also how we can give you access to information on who the important companies are, where they are, and how they can be contacted. When we have developed some options they will be run past the Biotech group to see if they meet your needs. In the meantime, more information specifically on biotech will be included in future issues of L@b Brief.

If you would like to raise any other issues or suggest things you would like us to do in relation to biotech, or anything else, please email: jacqueline.balian@gambica.org.uk

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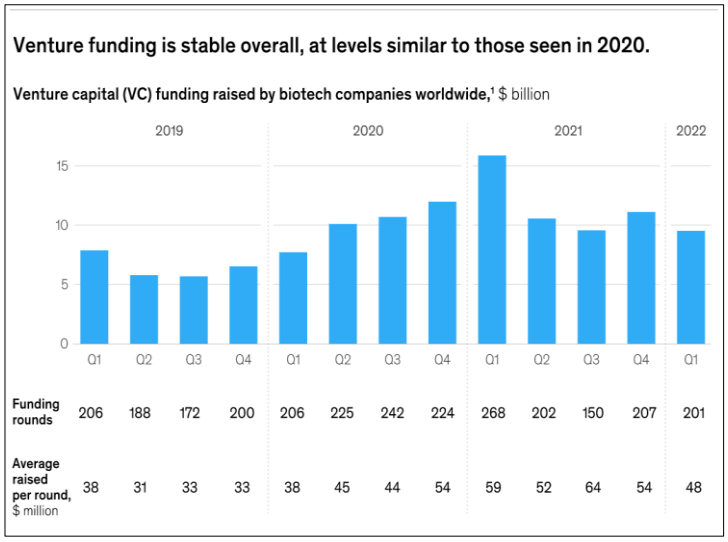
McKinsey hails Europes’ future in biotech

ACCORDING TO a recent report on the European biotech sector by business consultancy, McKinsey, biotech in Europe has an opportunity to lead the next phase of bioscience innovation.

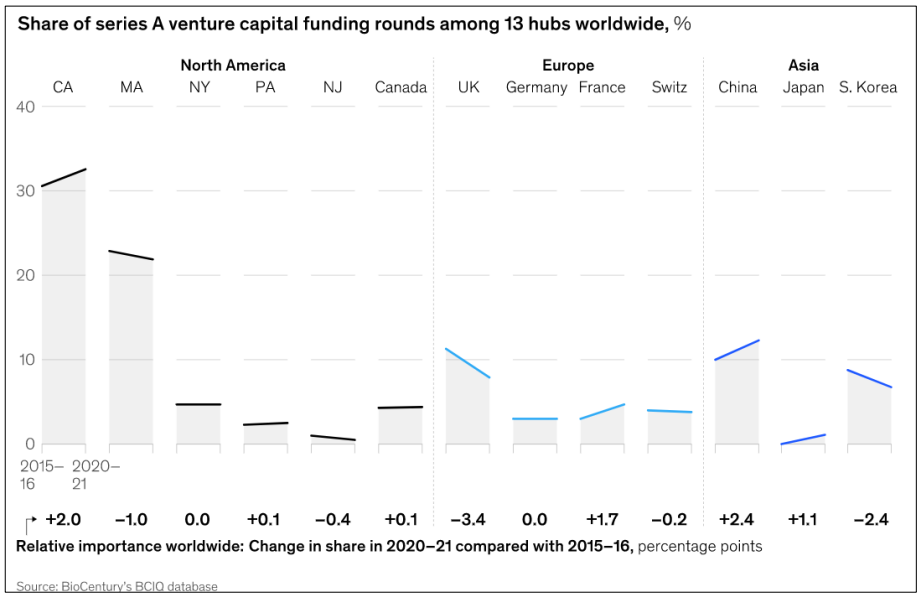
Although funding remains impressive, the 29 per cent drop in the Nasdaq biotechnology index from September 2021 to May 2022 made it much more challenging for biotech firms to secure public financing. After a torrid 2020, when biotechs raised a record $29 billion in capital globally through Initial Public Offerings (IPO), biotech IPO activity slowed in the second half of 2021 and virtually halted in the first half of 2022. Total capital raised through biotech IPOs worldwide in fourth quarter 2021 and first quarter 2022 fell by 63 per cent compared with the same period a year before.



As the financing environment continues to shift, the report predicts three likely developments:

1. *Big Pharma will deploy its cash stockpile.* Biotech firms could take advantage of the recent downturn in biotech valuations to embark on a wave of deal making.

2. *Biotechs will rely more on pharma partnering and private funding.* As the IPO window has narrowed, biotechs are increasingly looking for private sources of capital. The typical biotech is likely to adjust its path by delaying its IPO and acquiring more growth funding through private capital sources. In addition, we may see fewer new-product launches than in recent years.
3. *Cash will be managed and portfolios reprioritised.* While financing remains tight, biotech companies are likely to reprioritise their portfolios and manage cash more tightly to find viable paths to long-term value creation.



McKinsey consultants analysing the impressive levels of biotech innovation around the globe, found that Europe continues to be a scientific powerhouse: in 2021, it produced nearly 750,000 scientific publications, compared with approximately 400,000 in the United States. Publications from China have also accelerated in recent years, growing at an annual rate of 18 per cent between 2019 and 2021. More than 250,000 biotech patents were granted in Europe, China, and the United States from 2012 to 2021; nearly a quarter of them came from Europe.

US Food and Drug Administration (FDA) approvals have doubled, from 29 in 2011 to 60 in 2021, with 62 per cent of them first in class. European Medicines Agency (EMA) approvals have also ticked up from 80 per cent between 2011 and 2015 to 89 percent from 2016 to 2020.

The report agrees with other findings that the centre of innovation is moving from Big Pharma to start-ups. In 2003, the top ten pharma companies still accounted for 53 per cent of clinical trial enrolment but by 2021, the top ten firms enrolled only 18 per cent of clinical-trial participants.

Biotechs remain concentrated in distinct hubs, with limited shifts observed in the past five years.

Given healthy sector fundamentals and with strong financial support from private markets and partnerships, the authors believe that the European biotech sector has excellent potential to move forward and continue closing gaps with its US counterparts. However, Europe still lags behind the United States when it comes to translating promising academic research into start-ups. To access the full report, click here.

Launchpads to deliver local growth through innovation support

THE FIRST Launchpad pilot areas, part of an initiative designed to build on local innovation strengths by supporting SMEs, have been announced in Tees Valley and Liverpool City Region, with the first grant funding opportunities open for local businesses.

The Tees Valley Launchpad aims to support Tees Valley in becoming a regional hub for net zero innovation for Yorkshire, Humber and the North-East.

It will focus on:

- hydrogen
- carbon capture utilisation and storage
- offshore wind energy.

The Liverpool City Region Launchpad will focus on the advanced manufacturing sector, with digital technologies and net zero outcomes, building on the local economic strengths, research and development (R&D) assets, and strategic priorities.

Grants starting at £15,000 are available for business-led innovation projects, alongside wrap-around support for growth.

The Launchpad programme is a new Innovate UK innovation cluster development programme. The programme has an initial £15 million investment over three years to cover the first Launchpad pilot period and to help strengthen place-based innovation clusters in parts of the UK.

The key objective is to ensure more places in the UK host world-leading and globally connected innovation clusters, creating more jobs, growth, and productivity in those areas.

Following the announcement of the first two pilot Launchpads, the initial competitions are now open for bids from businesses in Tees Valley and Liverpool City Region to apply for grants. For more information click here.

£14 million awarded to smarten factories

UK RESEARCH and Innovation has announced the winners of almost £14 million in combined backing from its latest funding opportunity under the Made Smarter innovation challenge, the Sustainable Smart Factory competition.

The competition sought to identify and support digital innovations to improve the sustainability of manufacturing processes, resulting in either reduced material or energy consumption.

In total, 12 projects were successful in their applications, which involved securing between £1 million and £8 million in funding each and offering solutions for a wide range of manufactured goods and industrial processes across a number of sectors.

The winners include:

- Photocentric's solution for digitally manufactured, 3D-printed parts that can be created entirely autonomously and will challenge existing injection moulding techniques from overseas.
- Deep.Meta project, which will use novel artificial intelligence (AI) techniques to help reduce energy use and carbon emissions in the steel industry
- PragmatIC Semiconductor's project, which is looking to tackle the pollution within the electronics industry by building a new high-volume manufacturing facility that will help substantially reduce annual carbon emissions

Chris Needham, Innovation Lead of the Made Smarter innovation challenge said:

"Effective digital technologies can have a substantial impact on the manufacturing sector, bringing outdated, inefficient and unproductive products and processes up to the standards needed for a net zero industry of the future. It's clear from the wide range of applications we received just how far waste and energy issues extend across different industries.

"The successful applicants clearly demonstrated real innovation and showed just how the right use of data and technology can make a significant difference to businesses. We now look forward to working alongside them to deliver successful outcomes."

There are still further opportunities to get involved with the Made Smarter innovation challenge. The Made Smarter innovation digital supply chain innovation hub is also open for expressions of interest to run supply chain test beds.

The next collaborative research and development funding opportunity will launch in January 2023, offering a combined £6 million for industrial readiness robotics innovation projects within manufacturing operations.

For information, click here.

Can UKCA compliance be your competitive advantage?

GAMBICA's PROCESS instrumentation & Control Council has highlighted a lack of awareness within customer industries of the legal requirement for most products to be UKCA marked/compliant from 1st January 2023.

To help GAMBICA members turn the effort put into compliance into a competitive advantage, we have put together a bulletin to help ensure that customers are requesting UKCA-compliant products where necessary. To download the bulletin click here.

Opportunity to raise your profile at chemical laboratory exhibition

GAMBICA MEMBERS participating in Chem UK earlier this year had an opportunity to raise their profile among visitors by presenting at a GAMBICA organised seminar session. The

organisers of the event have been in touch to ask us to run similar sessions at the next event which is coming up on 10 and 11 May 2023.

A special ChemLAB section is to be added to the 2023 event with its own seminar stage. This will increase the opportunities available to GAMBICA members. Topics suggested by the organisers include:

- Analytical chemistry innovation /challenges
- Physical chemistry innovation / challenges
- Chemistry (organic/inorganic) enablers for future formulations & materials
- Biochemistry/IB enablers, for future formulations & materials
- Circular materials innovation/Materials discovery/Life cycle analysis
- Laboratory automation/innovation
- Wet Lab/Dry lab innovation
- Scale-up/Pilot programme innovation & strategy

Digitisation/Automation/Control & Instrumentation innovation in the process environment will centre on the 'Chem 4.0' stage and we will also have the opportunity to run sessions there. It is important that the seminars be well attended so we will be having a pre-meet to decide on compelling topics and session titles in advance. If you would like to present at Chem UK. Please drop me a line: Jacqueline.balian@gambica.org.uk

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Medtech incubator launches in West Midlands

UNIT 9 - A new medical technology incubator with facilities for medical research, proof of concept and prototyping activity has been launched in Birmingham.

Intended as a short-term incubator to bridge the gap for young companies that need space, equipment, and facilities, and do not have the funding for initial capital equipment the new space will help companies that are looking to develop innovative devices, medicines, procedures, or systems to solve a health problem or improve quality of life.

Dr Jamie Elliott, innovation lead for West Midlands Combined Authority, said: "Analysis identified a clear need for short-term laboratory space and the pilot incubator was endorsed by the West Midlands Innovation Board. This initiative strengthens our innovation

ecosystem and supports the region's ambitions of growing the health and medical technology cluster."

Unit 9 is based at the Birmingham Research Park, and will benefit from an equipment-sharing agreement with the University of Birmingham, and facilities for cell culture or microbiology work at the BioHub Birmingham.

LADS programme still on track

THE LABORATORY Agnostic Device Standard (LADS) programme which is looking to develop a standard communications and interoperability standard for all laboratory analytical devices, is due to complete its work next year, so we asked the team for an update on progress.

"It is true that we are nearing the end of the reference implementation period. We have been running implementations on different devices with a broad range of technology stacks based on the draft specification. So far we were able to realise:

- C(C99) / C++ (4 Teams)
- C# (3 Teams)
- JavaScript / Typescript (4 Teams)
- Java (1 Team)

"We are confident that out of these active implementations we are able to extract the two reference implementations required by the foundation. Since the specification is still in 'draft' status and the working group is still refining the spec the reference implementations can be finalised once we have a freeze in the spec.

"We have been able to cover a lot of ground before the summer break writing and testing the specification. I would like to emphasise the fact that we are testing what we put into the spec quite thoroughly.

"We are confident we will keep the set timeline for the release of the standard by Q4 2023."

The LADS management team would like to grow its working group with more people from device manufacturers. These people should be able to have approx. 2 days per week to invest into working on the spec and knowledge of the umbrella OPC Universal Architecture. Alternatively they are also seeking 'sponsors' who will be offered an onboarding presentation and the opportunity to organise a Hackathon in the UK.
If you would like to get involved in either capacity, please let me know.
Jacqueline.balian@gambica.org.uk

Upcoming GAMBICA Events

Decision-making and problem solving | 16 November | 10.30

GOOD DECISION-making is essential to the successful running of organisations, yet 61% of managers say most of their decision-making time is used ineffectively. If this sounds familiar, join us on 16 November to get yourself back on track.

Experts from executive training company, mypd, will give you a short refresher on decision-making and problem solving which is

part of their longer course developed for the Chartered Management Institute. To reserve your place click here.

Raman standards are changing – are you in the loop? | 8th November | 10.30

RAMAN SPECTROSCOPY has been experiencing a strong expansion in recent years; companies and research teams understand and appreciate many of the advantages of this technology. The technology is broadly standardised, but the way the standards are used in regulations is often complex, unclear and they are frequently misrepresented.

A team is currently working on a revision of the main standards which will have implications particularly for academic and regulated markets. This webinar will discuss the various existing standards and the correlation and correct use in regulated environments such as pharmaceutical markets and will run through the likely changes which will be included in the revised standards. The presenter will be Enrique Lozano Diz founder of ELODIZ Ltd. To reserve your place click here.

Refrigeration group meeting: progress on energy labelling regs | 11th November | 14.00

THE CASE for including laboratory refrigeration in the eco design and energy labelling regulations is about to go to the European Commission and I'm pleased to be able to tell you that the UK-led consultants are making good progress with the case for laboratory refrigeration to be included in the Eco design and energy labelling regulations. There are still some issues with the currently proposed test methodology for generating the data regarding (DIN 13277:2021), but it is felt that these could be ironed out (removing ambiguities; improving repeatability and reproducibility, improving compatibility of test method with usual energy label approaches). Lead consultant, Jeremy Tait has kindly agreed to provide a briefing for GAMBICA's refrigeration group members. The meeting will provide an opportunity to discuss how we might support the development of a more robust methodology - starting to address the main technical needs for an international standard, in advance of a formal standardisation request that might follow from the Commission in due course. To receive the joining instructions, please click here.

Successful formulas for doing business in the US | 29th November | 14.30

MANY GAMBICA members are thinking of initiating or scaling up sales in America, this webinar will help you avoid the pitfalls.

US legal expert Tom Thorelli, will offer insights on how to be successful in the US will cover:

• Distribution in the US – how to set up agreements and guard against poor performance;

• IP and trade mark management in the US;

• Your options for setting up an entity in the US; and

• Minimising legal risk in the US.

The US is a notoriously litigious society and Tom will be providing tips on how to avoid liability claims.

Tom is happy to provide free, half hour, one-to-one sessions before or after the webinar. Please email me if you would like to take up this offer. Jacqueline.balian@gambica.org.uk

To receive the joining instructions, please click here.

The four-day-week in practice | 5th December | 10.30

CAN MANUFACTURING companies adopt a four-day-week? Grant Instruments' HR Manager, Yasmin Mackay, and CEO, Mark Davison have already done it and will present this webinar about their experiences and how they achieved higher volumes, better productivity, improved staff welfare, and overhead savings – whilst still serving customer needs exactly as before. Grant CEO Mark Davison has been included in the Ones to Watch list in the LDC top 50 ambitious business leaders 2022. To receive your joining instructions, register here.

Export group meeting – Exporting to the US | 14th December | 14.00

THE NEXT export group meeting will focus on exporting to the US. We will have an expert speaker and invite ideas and questions

The presentation part of the meeting will cover how to market and sell laboratory products in the US, and will also offer insights into the often overlooked cultural communication differences that affect business outcomes. We are lucky to have Barbra Wells of GAMBICA member, Priorclave, as our expert speaker. Barbra has had great success in developing online sales in the US and she will be offering insights from her experience of what works and what doesn't. To register, click here.

Record-keeping and auditing for inward and outward processing | 11th January | 10.30

INWARD AND outward processing is here to stay - how to stay squeaky-clean when you are audited. Whether you are importing temporarily, of using the whole inward and outward processing set of options, HMRC is certain to be interested in your activities. Key to reducing the amount of time and effort involved when an inspector calls, is effective day-to-day record-keeping and regular correction of errors made elsewhere in the system.

To ensure that you don't spend more time on record-keeping than is warranted or necessary, Toby Spink of BKR Consultants will explain:

- How you can use IP (e.g. duty inversion, repairs, manufacturing)
- Benefits and opportunities (including case studies and examples of benefits)
- Record keeping, compliance, responsibility - how to get it right
- Solutions (e.g. out-sourcing, software, process design, record keeping)

BKR Consultants is a UK based customs and trade advisory company, working with importers and exporters across the globe. To reserve your place, click here.

Events

Disinfectant efficiency workshop | 2 & 3 November 2022

THE HSE is running a workshop which will help you to develop an understanding of the regulatory approach to efficacy assessment of disinfectant products. It will provide a general overview of the efficacy requirements for this type of product alongside specific advice for the five product types in this group. The workshop will also address common issues related to labelling and efficacy testing for these product types.

The workshop is suitable for those involved in the creation and submission of efficacy data packages for disinfectant biocidal product applications, including test houses, applicants, consultants, etc. To register click here.

HS Code Classification and the UK Global Tariff | 9 November 2022

CHAMBER INTERNATIONAL is running training on HS Code Classification and the UK Global Tariff and has made four places available to GAMBICA members at the special price of £321 plus VAT. Get in touch if you would like to be put on the list.
Jacqueline.balian@gambica.org.uk

BioTechX, Basel | 8-10 November 2022

THE BIOTECHX event runs across three days and features 400 speakers in 17 'tracks'. The event is free to attend for the first 400 pharma, academic and healthcare staff. Panel discussions include enabling access to healthcare data while protecting privacy. For information click here, to visit click here.

Future Surgery, London |15-16 November 2022

OVER 4,500 healthcare professionals from across the surgical sector will reunite in London on 15-16 November 2022 for the largest surgical event of the year which is designed for medical professionals. Ten exhibition spaces are still available. To register click here.

Orphan Drug Congress | Sitges Near Barcelona | 14-17 November 2022

THIS CONGRESS offers knowledge exchange and networking. Confirmed speakers include:

- **Magali Taiel,** Chief Medical Officer, Gensight BiologicsKeir Fitch
- **Thomas Bols,** Head of government affairs and public policy, EMEA & APAC**,** PTC Therapeutics
- **Fleur Chandler,** Head of Market Access UK and Ireland, Sanofi

- **Diego Ardigò,** Head of R&D, Global Rare Diseases, Chiesi group

For information click here.

BioFit partnering event for life sciences | Strasbourg | 29-30 November 2022

BIOFIT IS a European partnering event for technology transfer, academia-industry collaborations, early stage innovation deals and pre-seed, seed and Series A investment rounds in life sciences. It is expected to have over 1000 delegates from 35 countries and features conferences, pitch sessions, one-to-one meetings and an exhibition. For more information contact Marine Pentier, mpentier@eurasante.com or click here.

Maximising Returns from Life Science Innovation | London | 4-8 December 2022

LIFE SCIENCE body, One Nucleus, is running its annual conference, genesis 2022 on 7 December with fringe events taking place from 5-8 December.

The programme includes:

- A keynote programme covering winners and losers 2022, innovative deal making, technology-driven diversity in life sciences, a house debate and anatomy of a life science leader.
- Innovation workshops scheduled online around the in-person day.
- Online 1-2-1 partnering and an exhibition reserved for sponsors of the event.

For more information click here.

GENESIS 2022 | London | 5-8 December 2022

THE ANNUAL conference of biotech organisation, One Nucleus is for those researching, funding and developing innovative medicines and technologies takes place in person on 7 December at 1 Wimpole Street and online 5, 6, 8 December.

The event features an Innovation Support Hub Exhibition, (now sold out) including recruiters, trainers, suppliers and those offering state-of-the-art laboratory facilities but there are two premium sponsor exhibition booths remaining and the following delegate options are available:

- **Full Delegate:** access to all in-person and digital, 1-2-1 partnering and networking sessions (from £295 + VAT)
- **Digital Delegate:** access to all digital, 1-2-1 partnering and online networking sessions and on-demand recordings of the keynote programme post event (from £35 + VAT)
- **Innovation Workshop only Delegate:** access to all online Innovation Workshops scheduled across 5,6 & 8 December (£35 + VAT)
- **To register click** here. **To sponsor click** here

Export News

Export Partners UK presses new Minister on trade show access programme

EXPORT PARTNERS UK (EPUK), of which GAMBICA is a founder member, has sent a hard-hitting manifesto for a new UK Tradeshow and Mission Programme (UKTMP) to new minister at the Department for International Trade, Kemi Badenoch, saying that the DIT's UK Tradeshow Programme Pilot does not meet the needs of British business.

The manifesto argues that the current lack of structure of DIT support to companies puts the UK at a competitive disadvantage compared with the UK's key international competitors and demands that the Treasury change its view that trade promotion cannot be supported by public funds under WTO rules, as most of the UK's competitors (also WTO members) are already doing just, that very successfully.

"Industry is calling for industry-led and coordinated trade missions to markets where UK business people (not politicians) can meet overseas business people and do business. These are currently missing from the programme and are especially important in some of the UK's new FTA markets. Trade fairs and missions work, but they require the two things that only government can provide: money and the convening power of our Embassies and Consulates. Let industry do the rest," says the manifesto.

Calling for an integrated grant scheme to assist companies and industries to show at key international trade shows, the manifesto sets out the scale of the challenge facing exporters.

- In a survey of 60 UK industry bodies across all industry sectors in 2022, 98% identified that lack of government support for their potential exporters and a lack of sectoral activity and missions as the two largest threats to the UK's export drive.
- UK trade bodies have cancelled a large number of key events in key export markets due to lack of funding.
- UK SMEs with huge potential to start and expand exports with a turnover below £250,000 are now significantly less likely to launch into export shows than they were in 2019.
- The UK's major competitors are already believed to be back to 85% of their 2019 export figures, as their governments are investing heavily to support their suppliers.

It goes on: **"**Industry is calling for the UK to have a complete rethink on its trade show and mission policy and export promotion rationale, as companies try to get back on their feet after Covid and build new export markets after Brexit. Industry, industry representatives and government need to work *in partnership* for this to happen."

The only solution is a new UK Tradeshow and Mission Programme (UKTPM) says the manifesto:

- Invest more in building and expanding the UK's exports, in line with the UK's key WTO competitors for at least the next 5 years before a performance review in 2027.
- Provide UK companies with the tools to make a success of Brexit in markets around the world.
- Broaden the eligibility of the scheme to all UK SME companies registered for VAT in the UK or with a turnover above £83,000.
- Clarify the funding offer and simplify the application procedure for companies and ensure that application processes and deadlines match those space booking deadlines at the key exhibitions.
- Repair gaps in the skills and capabilities of the UK's Embassies and Consulates to streamline services and drive growth opportunities to companies of all sizes and independently review the effectiveness of other activity through DIT's outsourced delivery partners.
- Offer an integrated and joined-up programme of trade show support, trade missions, grants and research to meet the needs of individual companies and their specific industries (which often differ substantially) and the markets they sell to in the shorter and longer term.
- Confirm central **core funding** on a 3-year rolling basis of activity to rebuild the UK group presence at shows and to support companies and industries with physical and virtual content.

UK export support budgets (currently believed to be approximately £4m), EPUK alleges, are substantially underspent and compare extremely unfavourably with those of Germany, France, Italy, Spain, Turkey, Australia and other WTO countries, which annually invest well in advance of £20m each through industry-supported schemes. Italy typically gives exhibitors 80% grants on direct show costs. German businesses receive funding from national and regional government for most of the larger shows outside the EU. French companies receive generous grants of at least 60% through their industry bodies which are entrusted with looking out for new business opportunities for their companies.

Italy alone invests Eur 220m annually across all industries in the form of direct grants to companies at trade shows at home and internationally. Based on the painfully slow take-up of the UK's UK Tradeshow Programme (for reasons which have been explained), it seems likely that that UK's equivalent spend is closer to tens of thousands rather than even hundreds of thousands. At the same time, key human assets at the UK's Embassies and Consulates have been restrained or "let go" leaving DIT with little to justify its continued existence.

- For a copy of the manifesto click here. Members are encouraged to send it, along with a covering letter to their local MP.

Three Quebec hospitals to expand

THREE HOSPITALS in Quebec have issued contracts for major expansion works. The Hospital of Chicoutimi, Sept-Îles Hospital, and the Charles Le Moyne Hospital, are to have their operating rooms and specialised care units updated by Canada's SNC-Lavalin construction

company. The contracts have been awarded by the Société Québécoise des infrastructures (Quebec Infrastructure Corporation). Over the next five years, SNC-Lavalin's Engineering Services group and its consortium partners will provide design and engineering, site surveillance, building information modelling management, and value engineering.

Danish HQ of Ferring Pharmaceuticals opens

NEW LABORATORY spaces form the central part of Soundport, a six-storey triangular glass building and new Danish headquarters of Swedish firm Ferring Pharmaceuticals.

The total floor area of Soundport is 37,000 sq m, of which 24,000 sq m are office and lab space and is expected to house around 750 employees.

Privately owned Ferring is a leader in reproductive medicine, maternal health, and specialty areas within gastroenterology and urology.

Seqera Labs secures €22 million to power innovation in healthcare and life sciences

BARCELONA AND TORONTO-based company Seqera Labs, a startup providing data orchestration and workflow software for life sciences, has raised €22 million to expand its product portfolio.

The startup is helping the biotech sector operate in a more streamlined, efficient manner and have raised the money in Series A funding, building on its €4.4 million raise last year, plus several grants from the Chan Zuckerberg Initiative, founded by Mark Zuckerberg and Dr. Priscilla Chan.

Seqera Labs began life in Barcelona in 2018 as a spin-off from the Centre for Genomic Regulation (CRG), following the initial success of Nextflow. Nextflow, the popular open-source workflow and data orchestration software has become an industry standard among cloud providers, sequencing companies and genomics platforms. Today, Nextflow is used by thousands of organisations worldwide, is downloaded more than 55,000 times monthly, and is among the most successful open-source software projects in life sciences.

Hong Kong not doing enough to attract bio-tech

THE HONG KONG government is being urged to do more to build the city into a leading biotech hub after a luke warm reception to Chief Executive John Lee Ka-chiu's vow to "more actively and aggressively vie for companies and talent".

One of the measures set out by Lee Ka-chiu includes setting up the Office for Attracting Strategic Enterprises (OASES) to attract high-potential companies in hi-tech segments such

as biotech and artificial intelligence (AI) to the region. The government will offer favourable tax rates and fiscal aid to these firms, Lee said, and help with visas and the education needs.

The measures would complement Hong Kong's emergence as the largest biotech fundraising hub in Asia and the second largest in the world after it lowered thresholds for pre-revenue biotech companies in 2018. However, that status is under threat following a slide in stock prices in the past year, with the Hang Seng Biotech Index currently 64.2 per cent lower than its peak on June 28, 2021.

"Hong Kong should facilitate the integration of the local registration system with the one on the mainland," said Stanley Sy, chairman of Hong Kong Regen Medtech, which develops stem-cell therapies for intractable diseases, noting that Hong Kong does not have a primary review registration system for drugs and medical devices.

Nisa Leung, managing partner at venture capital firm Qiming Venture Partners, said the city should establish its own regulatory approval scheme for drugs and medical devices.

"Then we can actually very easily, potentially, have these drugs approved in the Greater Bay Area or in [mainland] China and elsewhere," she said.

Food and Drug Administration issues guide to avoiding drug shortages

THE FDA has issued new guidance for pharmaceutical companies on Risk Management Plans (RMPs) to mitigate the potential for drug shortages. It says that companies should analyse their supply chain and identify potential risk control strategies including:

- Identifying alternative / back up suppliers
- Building redundancy into manufacturing operations and overall supply chain
- Improving forecasting of demand changes at all stages of production
- Maintaining sustainable compliance
- Improving overall relationships with suppliers (contract manufacturers, raw materials etc)

Pretty much the minimum anyone might expect.

Wake-up call on trade finance fraud

THE INTERNATIONAL Chamber of Commerce United Kingdom (ICC UK) is pushing banks and authorities to accelerate adoption of digital export and import tools to help fight trade finance fraud, which it says could be costing up to US$5bn per year.

Trade finance lenders have invested heavily in tools to fight fraud but, the ICC says, these are being hampered by a lack of electronic transferable documents and cross-industry data sharing. "Legacy systems, poor market co-ordination, regulators not being proactive enough to enable banks to share data and governments being too passive are all part of the problem in preventing fraud," says Chris Southworth, secretary general of the ICC UK.

A webinar on paperless trade took place in October. To view the recording click here.

Drinks firm fined £30K for breaking sanctions

THE OFFICE for Financial Sanctions Implementation (OFSI) has announced that it has issued a £30,000 fine to drinks company Hong Kong International Wine and Spirits Competition Ltd (HKIWSC) for a breach of UK sanctions regulations.

HKIWSC was fined for its dealings with an entity that had been designated as a sanctions target by the EU following Russia's annexation of Crimea in 2014. OFSI took action even though the underlying transactions are of low value and its decision highlights that the provision of certain intangibles to a designated entity – in this case publicity – can in and of itself constitute an activity that breaches UK sanctions.

According to OFSI, HKIWSC received funds and wine bottles, worth under £4,000, from the designated entity for entry into competitions it ran. The wine bottles were considered to be frozen economic resources under the sanctions imposed against the designated entity.

OFSI also considered that the publicity HKIWSC made available to the designated entity following entry to the competitions constituted "an intangible economic resource" that also fell subject to the sanctions regime.

Company news

Autoclave manufacturer and service specialist, ESTS (GB) Ltd, joins GAMBICA

AUTOCLAVE MANUFACTURER, ESTS has recently joined GAMBICA, making five autoclave manufacturers in membership, and they make an effective group, getting together to draw up model standards and even considering sharing stands at overseas shows.

ESTS was founded some 20 years ago with the vision of producing innovative and high-quality autoclaves for healthcare, research and scientific laboratories. Initially providing service and support maintaining equipment from other manufacturers, the company quickly developed their own autoclave and are now the manufacturer of the Logiclave range of laboratory autoclaves and steam sterilizers. Designed and built wholly in the UK, the companies' products are well known for quality of build and reliability.

From the three founding directors the company has developed and grown and now employs a dedicated team of over 20 people operating from their base in Daventry, Northamptonshire. Currently headed up by director, David Hawtin and with an effective sales force including Victoria Chegwin, the ESTS team is keen to continue developing new products and services. They drew inspiration from the recent pandemic to increase their offerings in remote monitoring and diagnostics.

"We've added fantastic technological advances to reduce service and downtime namely Logiclave Remote and Logiclave Online. Logiclave Remote provides a secure remote access and fault diagnosis package for connectivity to each autoclave whilst Logiclave Online provides the ability to view and manage multiple autoclaves from a central location.

With WiFi connectivity available across the entire range, it is now possible to securely access both real time and historical data, alarm trends and machine status using a variety of devices such as

tablets, smart phones and laptops. Connection to wired networks and 4G cellular connectivity are also possible.

Alongside the ability to provide remote backup of historical cycle data, our engineers can now monitor and diagnose faults before attending site and in some cases even fix the issue remotely. Even if we can't tell operators over the phone how to deal with an issue, it means that when our engineer does arrive on site, he knows what the issue is and will already be fully prepared."
Currently remote monitoring and diagnostics is an optional extra but can be retrofitted to previous generation machines. With such a useful addition to their service capabilities, they are considering whether other organisations may wish to add it to their equipment, or allow them to add it on their behalf to take advantage of its potential to gather data on machine running times, process temperatures and pressures etc.
"We always recommend that autoclaves have some form of independent monitoring system, because although the equipment monitors itself, you really must have some form of verification. Generally, we fit a traditional printer or an electronic records system. However, independent monitoring is considered essential in hospitals and pharmaceuticals where record keeping is crucial"
"We have the ability to service a wide range of other manufacturers autoclaves and also a strong desire to work closely with our fellow manufacturers. Obviously, the majority of autoclave manufacturers will want to maintain their own equipment but there will always be some organisations who may have multiple autoclaves, all from different eras and different manufacturers who want to have only one service contract to take care of all of them. Having a team of engineers who have worked with multiple manufacturers over the years helps us to deliver this requirement."
"We are always open to collaborating with other manufacturers and service providers, especially on standards but also in other areas too, such as projects and the supply of equipment."
The company will be attending several upcoming exhibitions, including this year's Lab Innovations and the IDSc Annual Conference, whilst also looking towards future markets in Europe and the Middle East.
If you would like to get in touch with David, or with Victoria, you can get them via the company's website here.

Zero-emission transport focus of new UCL-HORIBA partnership at UCL East

UNIVERSITY COLLEGE London (UCL) researchers are closer to meeting the challenge of developing zero-emission transport, thanks to a new partnership between UCL and GAMBICA member, HORIBA.

The company will fund the HORIBA Chair in Advanced Propulsion Technologies as well as the work of two PhD students who will conduct research with them. This substantial

philanthropic donation will play a key role in shaping the next generation of engineers to drive vehicle technology.

The posts will sit within the UCL Advanced Propulsion Lab (APL), which will be based at the university's UCL East campus, which is opening over the next year on Queen Elizabeth Olympic Park. The APL is one of several cutting-edge new centres on the campus bringing together researchers, students, local communities and industry partners to collaborate on solutions to the biggest challenges facing people and the planet.

The APL will innovate in research techniques and train the next generation of specialist scientists and engineers to accelerate the move away from fossil fuels to clean energy transport options. It aims to provide the best facilities in the world to test vehicle propulsion, fuel cells and batteries – technologies key to achieving zero-emission transport.

Professor Nigel Titchener-Hooker, Dean of UCL Engineering, said: "The transport industry will be transformed over the coming years as we move to electric and hydrogen fuel cell vehicles. I am grateful to HORIBA for their support for the work of the APL and their commitment to working with us to lead this global transformation. UCL and HORIBA have the knowledge, skills, experience and facilities to be at the forefront of this exciting sector, driving forward technologies that are crucial to the future wellbeing of society and the planet."

HORIBA works in a range of fields, including engine emissions, scientific analysis, innovation for the future of the information society, healthcare, and environment monitoring. The company has long supported ground-breaking scientific research and innovation that drives change for society, by working in close collaboration with academia and industry leaders to accelerate and identify solutions that enable a sustainable future. Recent examples include partnerships with the Engineering and Physical Sciences Research Council Doctoral Training in Renewable Energy Northeast Universities (ReNU) and the Centre for Process Analytics and Control Technology (CPACT), which HORIBA has joined as industry partner.

Richard Carter, Director, HORIBA UK, said: "Through the provision of many years of technological competence and know-how, HORIBA goes beyond measure to support a cleaner and more energy efficient future. Thanks to the diversity in its technology and its ability to adapt and respond to industries' challenges, HORIBA is in a unique position to support the world as it evolves and remains committed to the realisation of a sustainable society. UCL is an ideal partner for us to pursue this commitment with.

"UCL is renowned for its globally-leading position in advanced propulsion technologies and, as the automotive industry heads towards an electric and hydrogen fuel cell future, we are delighted to be working in partnership with the APL and supporting the new Chair and PhD scholarships."

The UCL Advanced Propulsion Lab (APL) will open in 2023 on the UCL East campus.

***From left to right**: **Richard Carter**, Director, HORIBA UK, **Stuart Knight**, President, HORIBA UK, Prof **Paul Shearing**, UCL, and **Juichi Saito**, Executive Vice Chairman & HORIBA Group COO. **Copyright**: John Moloney Photography*

Company fined for workers' radiation exposure

A COMPANY which provides diagnostic imaging services, and its radiopharmaceutical subsidiary company, have been given six-figure fines following incidents at two sites in which employees were exposed to radiation levels in excess of the legal annual dose limit.

On 25 March 2019, a vial of a radioactive substance (FDG) leaked after it was installed into a shielded dispensing pot in the dispensing laboratory of Alliance Medical Limited's (AML) Positron emission tomography-computed tomography (PET-CT) facility at St James's University Hospital in Leeds.

This resulted in two members of staff becoming contaminated with skin doses in excess of the annual dose limit as defined by the Ionising Radiations Regulations 2017.

In a second incident, on 15 November 2019, the same radioactive substance was unknowingly handled during the production process at the Alliance Medical Radiopharmacy Limited (AMRL) facility at Keele University Science Park in Staffordshire.

Consequently, a member of staff was contaminated with a skin dose in excess of the annual dose limit as defined by the Ionising Radiations Regulations 2017.

An investigation by Health and Safety Executive (HSE) into the incident at the AML Leeds PET-CT centre found that training and instruction was inadequate and supervision below an acceptable standard. Staff were not made fully aware of the localised instructions and were using personal protective equipment (PPE) unsuitable for work with radioactive material.

A separate investigation by HSE found that at AMRL's facility at Keele University Science Park, the radiation warning system associated with the particular production equipment was not operational at the time of the incident and had not undergone routine maintenance and testing at suitable intervals.

Alliance Medical Limited, pleaded guilty to breaches of the Ionising Radiations Regulations 2017, Regulations 12, 18(3), 18(4) and 18(5)a, and were fined £300,000 and ordered to pay costs of £11,382 at Leeds Magistrates' Court Alliance Medical Radiopharmacy Limited, pleaded guilty to breaches of the Ionising Radiations Regulations 2017, Regulations 9(2)a, 11(1) and 12, and were fined £120,000 and ordered to pay costs of £11,382.