

L@b Brief | December 2024

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Hello again,



HOPE YOU are looking forward to the Christmas break – I certainly am, and it looks as if things may be turning more positive when we get back.

The Organisation for Economic Cooperation and Development (OECD) is predicting that growth will remain resilient in 2025 and 2026 although it does acknowledge some significant risks.

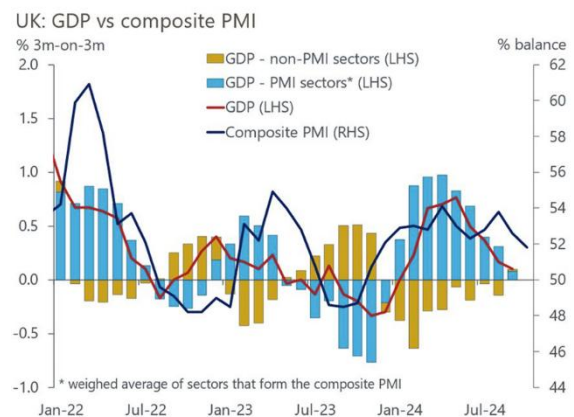
In its latest [Economic Outlook](#) it predicts global GDP growth of 3.3% in 2025, up from 3.2% in 2024, and 3.3% in 2026.

Inflation in the OECD is also expected to ease further, from 5.4% in 2024 to 3.8% in 2025 and 3.0% in 2026.

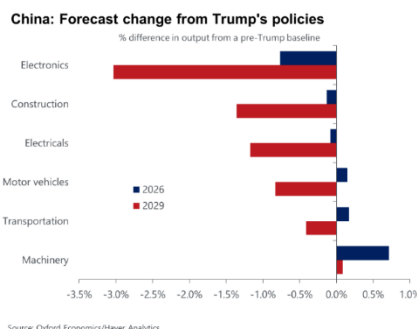
Other forecasts have been more mixed. The latest report from European Tech body, Orgalim highlights a significant decline in demand across various sectors, with 2024 projected to see a 4.8% drop in real turnover for the technology industries. This downturn is attributed to a combination of factors, including weak demand in the automotive sector, particularly for electric vehicles, and reduced demand from both the USA and China.

So how should we interpret these mixed signals? Well, a forecast specifically for our industries by Oxford Economics, highlighted some issues with data gathering. Noting that forecasts are exaggerating positive economic performance in the first half of the year, and making the second half look much worse by comparison.

Chart 1: Noisy data probably exaggerates the loss of momentum in Q3



Sources: Oxford Economics, ONS, S&P Global



They also have some positive comments on the chemicals and pharmaceuticals industries, which they expect to increase production by 1.7% and 1.2% respectively in 2025. OE also indicate that the Trump presidency is unlikely to have any serious a negative impact on UK although it will have a negative impact on our competitors.

The Oxford Economics report is a detailed, 40 page, forensic look at our sectors, identifying the factors which will impact on us next year. It is produced for GAMBICA members on a shared cost basis, if you would like a copy, you can order one through the website, [here](#). The more general OECD report is available [here](#).

Whatever we encounter when we return next year, have a very happy Christmas break. Toodle pip!

Jacqueline

UK News

Set aside one day to focus on sales growth for 2025

YOUR GAMBICA conference in March will be a full day of information and insights with one target: to empower you to grow your sales in 2025.



This year we are dedicating a full session to sales across Europe. We have recruited two specialist sales trainers with specific laboratory sales expertise across Europe to explain how to avoid blunders in business and give you an effective model for sales growth.

Swiss-based consultant, Christian Walter, ex of Mettler Toledo and Buchi, with specialist lab sales trainer Jayne Green from George

James, will focus on cultural differences and how the sales process should be adapted for markets in France, Germany, Italy, Switzerland and the UK.

You will come away empowered to standardise as much as possible, and adapt as much as necessary.

This sales training will be part of a day which will inform you on directions and developments in research and research funding priorities and what these major movements mean for equipment providers.

It will also set out the wider economic framework in which your clients will be operating.

If you are serious about growing in 2025, you can't afford to miss this day.

To book your place at the conference click [here](#).

We have a very few places still available to join the conference dinner the night before and to

stay over at the Barnsdale. If you would like to meet senior GAMBICA members socially before the conference, you should book your place immediately!

Look forward to seeing you there!



Full conference programme...

Tuesday 11th March 2025

Venue: The Barnsdale Hall Hotel, Oakham, Rutland, LE15 8AH

Lab customers: their requirements - our future	
08.30 / 09.00	Conference registration and refreshments
	SESSION ONE: FORECASTS FOR THE COMING YEAR
09.00	Welcome: Jenny O’Connell, Chair, GAMBICA Lab Tech Board
09.05	Political forecast: The UK in Europe under the new government: Anand Menon
09.30	Economic forecast: Lee Hopley, Director, Economic insight and research, UK Finance
09.50	The future of lab sales: Joshua Chapman, SLS
10.10	Update for GAMBICA Members: Steve Brambley
10.25	Refreshments
	SESSION TWO: HOW THE LAB IS CHANGING
11.00	Nature-inspired engineering – the way of the future: Prof Marc-Olivier Coppens, UCL
11.30	Innovation in bio-based systems; challenges, future and funding Jenny Readman UK-Centre for Process Innovation
11.50	Formulating biology; challenges for lab suppliers in the growth of biochemistry: David Calvert
12.10	How continuous training drives instrument performance and maximizes ROI for suppliers - <i>Unlocking value by partnering with lab technicians and researchers through training:</i> Dr Han Wu, UCL
12.30	Q and A panel session
13.00	Lunch
	SESSION THREE: WHAT CUSTOMERS WANT
14.15	What pharmaceutical clients want from their suppliers – Chris Neasham, Associate Director – Almac Science Procurement – global leader in drug development
14.40	How university purchasing is changing, sustainability requirements and the pipeline of tenders: Lisa Blackburn NWUPC
15.05	Carbon metrics for chillers and biotech products - how we are going about it: Grant and Eppendorf
15.25	Refreshments
	SESSION FOUR: INCREASING SALES
15.45 – 16.15	Sales – what’s working right now – in the UK and in Europe Jayne Green and Christian Walter from George James
16.15 - 16.20	Results of business sentiment survey and close

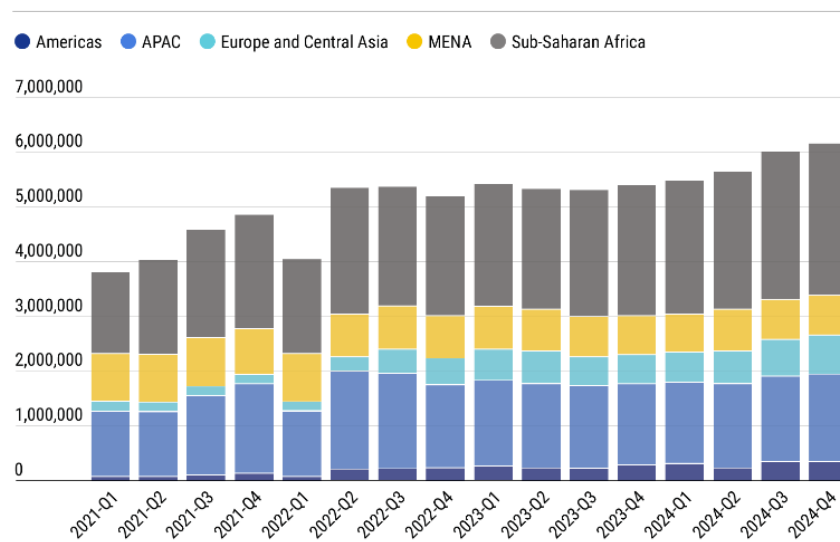
Cost of doing business hits ten-year high as tensions disrupt trade

THE RISING tide of ‘deglobalisation’ and protectionist policies has driven global business costs to their highest levels in a decade according to the latest analysis from risk assessors Verisk Maplecroft.

Pointing to escalating geopolitical tensions, particularly between the US and China, and a growing number of trade restrictions and tariffs placing significant strain on businesses, especially in Western democracies, the report notes that companies in the UK, US, Germany, and Japan are also seeing rising operational costs, including higher taxes, labour expenses, and borrowing costs.

Territory impacted by conflict has increased by 65% since 2021

Territory impacted by conflict (km²) per region, 2021-2024



Global analysis excludes Antarctica.

Conflict-affected areas encompass territory proximate to and where fighting is ongoing.

Source: Verisk Maplecroft, ACLED

© Verisk Maplecroft 2024

Rising costs are directly linked to increasing trade barriers and tit-for-tat measures between major geopolitical blocs. The cumulative effect of the ongoing trade war from 2018 to 2023 has been estimated to cost the global economy between \$1.5 trillion and \$2 trillion.

Since 2018, many of the world’s major economies, representing about 45% of global GDP, have seen declines in

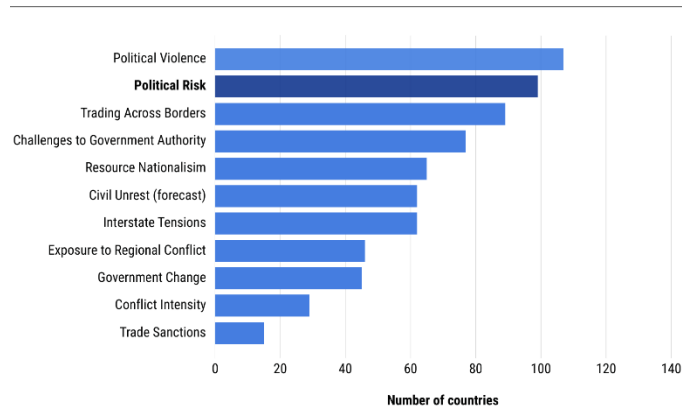
their business environments due to protectionist policies. Measures like higher import tariffs, export controls, national security-based investment screenings, and protectionist subsidies have mostly failed to improve the broader business climate.

The US, UK, and South Korea have seen the steepest increases in business costs, while countries like Germany and France have experienced rising borrowing costs. This cost escalation largely stems from trade measures targeting critical industrial sectors such as steel, agriculture, auto parts, and pharmaceuticals. In contrast, China has demonstrated greater resilience, despite being a primary target of trade sanctions.

As the US-China trade relationship weakens, both countries are increasingly turning to key ‘connector’ economies like Mexico and Vietnam. These countries have significantly increased their share of US imports and captured a larger portion of Chinese exports and foreign direct investment (FDI). However, these countries present new risks for businesses. Mexico, with its high crime rates and violence levels, and Vietnam, with worsening labour

rights concerns, pose operational and security risks for businesses expanding into these markets.

Number of countries that have recorded a significant increase in risk since 2021-Q1



Source: Verisk Maplecroft

© Verisk Maplecroft 2024

The rise of ‘connector’ economies could soften the economic fallout from the ongoing trade war, but the broader shift towards regional trade blocs is likely to drive up costs and reduce global trade efficiency. This is particularly challenging for small and medium-sized enterprises (SMEs), which rely heavily on international exports. As costs rise, SMEs could face financial instability and an increased risk of default, which could disrupt multinational supply chains that

depend on them.

As global economies increasingly align into three major blocs—the US-led bloc, the China-led bloc, and a third group of nonaligned nations—rising protectionism is expected to erode corporate margins and competitiveness. Companies headquartered outside of the US are particularly vulnerable, with SMEs facing the toughest challenges.

To download the full report, click [here](#).

EU urged to tackle deteriorating competitiveness

Leaders of Europe’s high-tech manufacturing industries, have expressed alarm at Europe’s



decline in competitiveness saying that Europe is at risk of permanently falling behind the world’s leading economies.

In 2024, EU GDP is forecast to grow by just 1%, compared with 2.4% in the US and 3.2% in the world as a whole. Lower productivity is said to be a major contributing factor to Europe’s slow growth. In 1995, the EU and the US had similar rates of productivity. However, today, EU productivity is about 20% below the US.

Javier Ormazabal, President of Orgalim, which represents Europe’s high tech industries, commented: “Our citizens’ continued welfare, security and environmental standards depend on a vibrant European economy. If we cannot close the competitiveness gap that has opened up, I am deeply concerned that the European way of life as we know it will face a decisive challenge.”

Orgalim says it is essential that the EU’s leaders tackle: “the stifling regulatory burden weighing down our industries. Between 2019 and 2024, the EU passed 13,000 pieces of legislation, many of which are needlessly prescriptive, unclear and incoherent and are

holding back growth and productivity in our industries. By comparison, the US adopted 3,500 pieces of legislation at federal level in the same period.”
For more information, click [here](#).

Research update: New partnership to provide ‘epigenetic map’



A NEW partnership planned between the government, Oxford Nanopore, Genomics England, UK Biobank, and NHS England is to use Oxford Nanopore’s genetic sequencing tech to analyse 50,000 samples to create a world-first ‘epigenetic map’; the World’s first comprehensive dataset of epigenetic modification in the human genome. The aim is to unlock new insights

into the causes of diseases like cancer, heart disease and dementia.

Epigenetics is the study of how inheritable traits – such as the risk of developing a certain disease – can emerge and change without actual changes in our DNA code, but rather as a result of modifications that change how our genes are expressed. These modifications can arise randomly, but also in response to environmental factors like smoking or UV exposure. Professor Naomi Allen, Chief Scientist, UK Biobank, said: Our lifestyle and environment can cause chemical changes to our DNA, which can contribute to disease by altering the ways genes tell the body which proteins to produce. By understanding these chemical changes, known as epigenetics, we can learn why some people fall ill and others don’t, even when they share the same genes.

“Right now, researchers only have small amounts of epigenetic data to study – this project will create a dataset unlike anything else in the world. It is orders of magnitude bigger, and because of the technology, the data will be much more detailed.”

UK Carbon Border Adjustment Mechanism to go ahead



A UK Carbon Border Adjustment Mechanism (CBAM) largely mirroring that being instituted in the EU, is to go ahead the government has announced. It will place a carbon price on emissions-intensive industrial goods from overseas including; aluminium, cement, fertiliser, hydrogen and iron and steel sectors where it is considered that there is a risk of ‘carbon leakage’ (where UK companies minimise their own carbon emissions by buying in materials produced overseas,

often by carbon intensive means).

New guidance has been produced for comment which includes a draft list of HS commodity codes for inclusion. The UK CBAM will be largely, but not wholly, on the terms set out in last year's consultation.

But there are some key changes:

- The government has increased the minimum registration threshold so only those importing £50,000 or more of CBAM goods over a 12 month period will need to comply. 70% of the companies removed from CBAM reporting by this are micro, small, or medium sized businesses.
- Products from the glass and ceramic sectors will not be in scope of the UK CBAM from 2027 as previously proposed.
- The response also clarifies the position on goods subject to outward processing and re-import to the UK.

The Government is stressing that:

- Implementation by 2027 will allow government to consult fully with those affected throughout the design and implementation phases.
- It will also give UK and overseas businesses more time to prepare and put appropriate processes in place with their supply chains to enable them to comply.
- Given the EU CBAM charges will be introduced gradually from 2026 to 2034. 2026 charges will be relatively small (which implies risk of diversion will be smaller than in latter years).

The Finance Bill will be used to legislate to allow HMRC to start spending on the necessary IT systems, and enabling data held under the UK Emissions Trading Scheme (ETS) to be shared with HMT and HMRC to support development and implementation.

Click [here](#) for the full consultation.

OECD issues paper on Good Laboratory Practice and IT security

The Organisation for Economic Co-operation and Development (OECD) has issued a position paper developed by its Working Party on Good Laboratory Practice (GLP) which sets out a standard for the approach to cyber security for laboratories working to Good Clinical Practice (GCP) standards.

This position paper addresses issues around electronic GLP data and linked computerised systems hosted in servers and subject to computerised corruptions it doesn't contain anything unexpected but members may like to confirm to clients that they are aware of and comply with its requirements. To download the position paper, click [here](#).

Laboratory Construction Update

£4.5 m project to boost Edinburgh life sciences sector

[Edinburgh](#) is to become a base for a multi-million-pound project to help address an 'acute' skills shortage in the life sciences sector.



The new initiative, known as Resilience, aims to tackle the skills shortage faced by the medicines manufacturing industry in the UK. Heriot-Watt University will be one of the partners delivering the programme which is funded by the Office for Life Sciences through Innovate UK. Resilience is a £4.5 million, two-year programme.

The UK's first Medicines Manufacturing Skills Centre of Excellence will also use [virtual reality](#) to train in laboratory skills and support the NHS's net zero goal.

The new Edinburgh-based Centre of Excellence will also use virtual reality to train in laboratory skills.

Norwich Research Park poised for rapid growth in 2025



Norwich Research Park is set for ambitious expansion in 2025, according to Anglia Innovation Partnership. The park has become a hub for innovative companies that have developed their ideas through campus research. It also benefits from a recent partnership with Vengrove, a real estate investment expert, allowing for the construction of state-of-the-art office and laboratory spaces expected to begin in

early 2025.

To further support innovation, Greensphere Capital has launched the Gaia Sciences Innovation partnership, providing access to £75 million in funding—projected to rise to £100 million by early 2025—for startups focused on climate change and biodiversity. This funding will benefit businesses from key institutions such as the Earlham Institute and the John Innes Centre.

With substantial backing from UKRI and BBSRC, Norwich Research Park is solidifying its status as a leading bioscience research hub. CEO Roz Bird highlighted the park's unique position and its potential for growth, while the recent launch of the Enterprise Strategy aims to nurture new startups.

Kenyan government to begin constructing 2600 labs in secondary schools in January 2025

The Kenyan government has pledged to construct 2,600 laboratories in secondary schools. Dr. Belio Kipsang, Principal Secretary for the State Department for Basic Education,

announced that 1,600 physical laboratories will be built in schools lacking these facilities, ensuring that every secondary school has at least one lab by 2026. Additionally, 2,000 virtual laboratories will be established to enhance Science, Technology, Engineering, and Mathematics (STEM) education.

Laboratory of the future in Vienna reaches construction milestone

Global pharmaceutical company, Takeda has reached the topping out stage of construction of its new Total Quality Building (TQB) dedicated to research and development. The building, in Vienna's Seestadt Aspern, will accommodate up to 250 scientists.

Andy Plump, President of R&D at Takeda, emphasised the importance of this investment for local innovation and collaboration, reinforcing Austria's role as a key centre for Takeda's research efforts. The facility will feature flexible laboratory spaces consolidates Takeda's R&D activities from five locations into one. The project is expected to create new jobs and further solidify Vienna's position as a leading life sciences hub in Europe.

Upcoming GAMBICA Events

Benefits of sustainability standards & mapping a path to Net Zero| online | 21 January 2025 | 10.30 - 11.30



IF YOU are thinking of starting on a journey to Net Zero, the choice of path and priorities can be very confusing. There are now a whole range of sustainability standards each with the potential to play a part in your green transition. In this webinar, experts from leading ISO consultancy, Blackmores, will describe the purpose of each standard along with its benefits and disadvantages. They will then provide a deep dive into how or how far, each might meet your particular needs. Finally, the session will provide a run through of how you can use ISO 14068 to plan your path to Net Zero.

The webinar will cover:

- ISO 14001 Environmental Management – Benefits and disadvantages
- ISO 50001 Energy Management - Benefits and disadvantages
- ISO 20400 Sustainable Procurement - Benefits and disadvantages
- How can sustainability standards support you?
- What is ISO 14064 and ISO 14068?
- Calculating GHG (Green House Gas) Emissions across scopes 1,2 & 3
- Reducing your current environmental impact
- Re-quantifying your emissions
- Offsetting remaining emissions – What options are available?

To reserve your place, click [here](#).

The Service Team as company ambassadors – shared cost training | GAMBICA offices, London | 28 January 2025 | 09.00- 17.00



THE LATEST in the shared cost training being provided for members by GAMBICA will be a one-day workshop on *The service team as company ambassadors*.

This training has proved very popular with members offering servicing in the past. It is designed to inspire those in Service Teams – both Service Engineers and those who provide team support – to realise the importance of their contribution.

It will develop their sense of purpose and encourage them to see themselves, directly or indirectly, as a key player in your company's business success.

The day will build on their experience of customer service and will develop their ability to handle a wide range of client situations with confidence. It will also help develop further their organisations' reputation for excellent service.

What delegates will learn

- Their vital role as service engineers and service team members in the business growth of their company.
- How to contribute to their role in providing their organisations with a 'competitive edge'.
- How to listen and understand to client needs more effectively and to respond to them successfully.
- How a little extra effort during a service call can develop opportunities that contribute to ongoing sales.
- How to develop stronger and more positive client relationships.
- Techniques for handling difficult situations.
- That they are valued professionals with a key role in their organisation's ongoing success.

Training methods

The day will build on and share experience of those attending and will focus on developing an Action Plan to deliver excellent client service in everyday business. Practical exercises, discussions and group work will form a key part of the workshop – which will be practical, relevant and fun.

The range of costs will be between £250 and £550pp depending on numbers. If you would like to reserve a place on this training, please do so [here](#). We will contact you when we know how many people want to book to tell you what the cost will be. You will be invoiced direct if you wish to go ahead.

Board gap analysis in preparation for acquisition – finding your place | online | 11 February 2025 | 10.30 - 11.30



WITH INCREASING acquisition activity in the laboratory industry, many more people are thinking about how to prepare themselves and their company for external scrutiny. Demonstrating that you have the skills to take your company to the next level requires careful analysis of your current skills set and what is required to take the company further. From a company point of view, those preparing to seek

investment need to analyse their c-suite and non-execs to make sure that they have the range of experience and aptitudes required. In this webinar Andrew Moore of tech sector executive recruitment firm Bailey Fisher will explain how directors should undertake the necessary skills gap analysis, and how individual staff members can review their own progress and identify the means to progress their careers as their company develops.

To register for your place, click [here](#).

Selling through distributors – shared cost training | GAMBICA offices, London | 28th and 29th April 2025 | 09.00 - 17.00



WE ARE delighted to be able to offer GAMBICA members specialist training in selling through and managing channel partners. This training has been specifically developed for the lab industry by trainers with huge experience in our industry, Sharon Eaton of BioChannel Partners and Steve Vaughan of George James. This training normally costs £3600 per person,

but it is available through GAMBICA as shared cost training which could cost as little as £750pp if 12 people register.

THE TRAINING CONTENT IS AS FOLLOWS:

DAY 1	DAY 2
<p>Module 1: Channel partner skill development</p> <ul style="list-style-type: none"> • The role model channel partner manager • Developing personal goals • Prioritising a focused workload • Managing v Leading skills • Communication & listening skills <p>Module 2: Channel partner management planning</p> <ul style="list-style-type: none"> • Business plan development • Current situation audit & gap analysis • Defining best partner profile for optimal coverage • Channel partner recruitment process • Planning and managing growth 	<p>Module 3: Managing Channel Partners</p> <ul style="list-style-type: none"> • Managing channel partner performance • Managing targets and sales funnels • Business reviews with your channel partners • Managing channel conflicts • Managing under-performance, recovery and termination <p>Module 4: Influencing channel partners</p> <ul style="list-style-type: none"> • Assessing capability and willingness • Managing power imbalances • Channel partner motivation • Constructive feedback • Developing trusting relationships

This training is being offered by GAMBICA on a shared-cost basis, the more people who attend, the lower the per person price will be. Please register your interest [here](#) and Sarah Wicks (sarah.wicks@gambica.org.uk) will inform you about the cost per person and invoice you nearer the date.

We can accommodate between 6 and 12 people and the cost will be between £1500 plus VAT per person (if six people attend) and £750 per person (if 12 book).

INDUSTRY events

Global innovation and new technology health event | London | 9-10 December 2024

THIS EVENT is described as the NHS innovation festival and comprises the UK National ICS congress, the mental health technology show, the future hospital show, the women's health technology show and the net zero technology show. For more information click [here](#).

Biopharma and life sciences connected | Cork, Ireland | 23 January 2025

THE THIRD annual [Biopharma & Life Sciences Connected](#) event will be held at the Radisson Blu Hotel, Little Island, Cork bringing together 1,000 senior managers from industry, academia and government support agencies responsible for nurturing growth and investment in the biopharma sector. The agenda includes three separate stages, cover digital transformation, sustainability, skills and training, capital investment, regulations and much more. Click [HERE](#) to watch a short video from the 2024 event. There are a limited number of table-top exhibition slots available @ €2,195. For more information click [here](#).

SLAS Europe technology provider showcase | San Diego | 25-29 January 2025

FOCUSED ON interconnectivity, technology and discovery, the SLAS event provides a deep dive into laboratory automation, innovation and analytics. The event is especially targeted at the pharma industries and offers an 'Omics and spatial omics track' and a 'screening applications and biomarker diagnostics track. For more information click [here](#).

CIM2025 International Metrology Congress | Lyon | 11-14 March 2025

CO-LOCATED WITH France's largest industrial trade show this event aims to be a hub where science, industry and metrology players come together. For more information, click [here](#).

London Lab Live | ExCel London | 14-15 May 2025

THE SUCCESSFUL Future Labs Live Basel event is to be replicated in London from 2025, with the organisers, UK firm Terrapin, expecting over 100 speakers 150 exhibitors and 3000 attendees. The focus of the conference will be on lab informatics, digitalisation, IOT and cloud services. To exhibit or attend, click [here](#).

Solutions in Science | Cardiff | 8-10 July 2025

FEEDBACK FROM visitors to the last SinS conference in June 2023 was positive and the next event has now been scheduled to take place in Brighton. The aim of SinS is to showcase complementary and diverse ranges of analytical instruments, technologies, applications and present solutions to scientists from a range of industries and academic disciplines. To book your exhibition stand contact Chris Jarvis chris@intlabmate.com 01727 855574.

Upcoming tenders

Prior Information Notice for new framework issued

North Western Universities Purchasing Consortium has published a Prior Information Notice (PIN) for the upcoming Medical Simulation & Training Framework Agreement Ref: LAB3032 NW. The link to the notice on Find A Tender can be found here: [Medical Simulation and Training Equipment. - Find a Tender](#),. There is a market survey and slide deck included within the notice.

Frequency Comb Laser Amplifier

CERN has recently released a price enquiry reference DO-34218 for the supply of a Frequency Comb Laser Amplifier to 100 W to amplify ultrafast laser pulses produced by an ultra-low-noise mode-locked laser oscillator from 10 mW to 100 W level.

This price enquiry is valued between 50-200K CHF. Price enquiries are not publicly available and in the first instance, CERN selects firms to respond from those put forward. Only UK companies will be forwarded by STF.

If you have any interest in this price enquiry please contact Julie:

tenderopportunities@stfc.ukri.org by 17/01/2025

For more information on Doing Business with CERN and to register on their supplier portal, please visit their webpage: [Supplier Portal | Procurement and Industrial Services Group \(cern.ch\)](#)

Strengthening UK microbial forensic capability

The [Defence Science and Technology Laboratory \(Dstl\)](#), has launched a new competition called '[Future-proofing biosecurity by strengthening the UK's microbial forensic capability](#).'

The initiative is funded by the MOD. The total possible funding available for this competition is £1 million (excluding VAT) and the competition closes midday on Tuesday 18th February 2025 (GMT)

To learn more and submit your proposal, click [here](#)

Export News

Free trade agreements come into effect

The UK's accession to CPTPP (the Comprehensive and Progressive Agreement for Trans-Pacific Partnership) will take place on 15th December 2024. This means that UK traders can start to use the CPTPP terms from this date with those countries that have ratified the UK's accession. From LATAM, this is Peru and Chile. Once Mexico ratifies the UK's membership- UK companies will be able to use CPTPP, 60 days from that official date.

Specialist guidance is now available on www.great.gov.uk and the [check your duties and customs website](#) will be updated to reflect the CPTPP tariffs.

Costa Rica has been confirmed as the next candidate to potentially join CPTPP. Ahead of this taking place the UK Government is keen to hear from you about the eligibility of Costa Rica as a candidate. Submit your views [here](#) until 24th January 2025. It should take 10 minutes to complete the questionnaire.

China brings in new rules on reagents and local manufacture...

A draft update to China's IVD Reagents Clinical Trial Exemption Catalogue has been released by the Center for Medical Device Evaluation (CMDE) for public consultation.

It lists products that do not require clinical trials due to their established safety and efficacy profiles. And the CMDE now aims to expand the products listed, reflecting advancements in diagnostic technology and increasing clinical demand. By doing so, they seek to reduce regulatory barriers, accelerate market access for innovative products, and address pressing public health needs.

Invitation for feedback

The CMDE is inviting feedback from industry stakeholders, including manufacturers, regulatory professionals, and clinical experts. This consultation process is an opportunity to propose revisions, suggest new products, or provide justifications for changes to the catalogue. Feedback can be provided in the following categories:

- Proposed Additions: New products to be included in the draft catalogue.
- Revisions: Changes to the products listed in the 2024 draft.
- Updates to the 2021 Catalogue: Revisions to products included in the previously published exemption catalogue.

Comments can address serial numbers, product categories, intended uses, and regulatory classifications. Stakeholders are encouraged to use the feedback form provided in Appendix and submit responses via email to huangyl@cmde.org.cn by December 3, 2024. The subject line should read: *"Feedback on the 2024 Exemption Catalogue of In Vitro Diagnostic Reagents."*

Rules clarified for those wanting to manufacture medical devices in China

China's policy on the domestic production of imported medical devices has been released by the National Medical Products Administration (NMPA). This draft aims to clarify the regulatory requirements for foreign-invested enterprises seeking to manufacture imported medical devices domestically.

The draft applies to foreign-invested enterprises established by registrants of imported medical devices or those with the same legal owner. These enterprises are permitted to manufacture Class II or III medical devices that have already been granted registration certificates for import.

It introduces streamlined processes for registration, allowing applicants to use data from previously approved registrations of imported devices. Key requirements include:

- Updated technical standards and inspection reports reflecting compliance with applicable mandatory standards.
- Supporting documentation to verify the current legal owner and their relationship with the registrant.
- Notarised authorisation from the registrant to allow domestic production using previously submitted registration data.

By simplifying the use of existing data, the NMPA aims to encourage foreign-invested enterprises to transition to domestic production without compromising product quality or regulatory oversight.

Applicants are required to demonstrate that domestic production processes align with China's Good Manufacturing Practice (GMP) for Medical Devices. Additionally, they must provide:

- A self-inspection report comparing domestic and international quality management systems.
- Risk analyses for any discrepancies, ensuring safety, effectiveness, and quality remain uncompromised.

Authorities will conduct comprehensive QMS verifications, with a particular focus on design, development, and equivalence between domestic and imported systems.

Stakeholders are encouraged to review the draft policy and submit their feedback to ylqxzc@nmpa.gov.cn with the subject line "Feedback on Import to Production".

Read the original NMPA announcement on [China Domestic Production of Imported Medical Devices](#).

Company news

Specialist in cell disruption joins GAMBICA

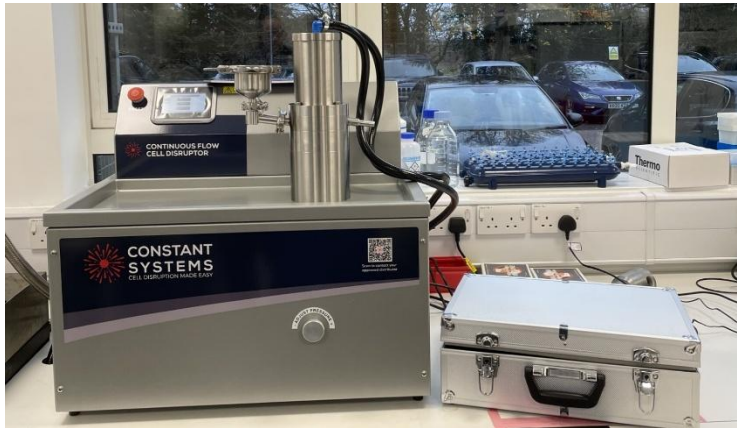
Newest GAMBICA member, **Constant Systems Limited**, produces high accuracy cell disruption equipment designed to break open cells in a controlled and efficient manner. The objective is to extract intracellular components like proteins, nucleic acids, organelle and other biomolecules. The means by which Constant Systems' equipment does this, preserves the integrity of these biomolecules, ensuring functionality and structure for downstream analysis. Their systems are known for precision, reproducibility, and scalability, serving a wide range of applications in research



and industry, to include Academia, Contract Research (CDMO), Biotech and Pharma sectors.

Current growth for Constant Systems has much to do with its reputation for quality equipment and superb service and aftermarket support. The Northants based company sends its UK engineering staff around the world to install its highly sophisticated equipment to ensure the clients expectations are met and the experience is a good one from the start and a particular strength is its onsite training. Delivering total satisfaction brings with it great customer relationships and fun with regular trips to the US, Canada, Australia, Saudi Arabia and South Africa too for their engineers!

Cell disruption is a technique used to extract the contents of cells (often yeasts or bacteria) which have been engineered to over-produce desirable biomolecules. Other laboratories use mammalian cell models to elucidate receptor binding functions or determine the protein structure of membrane bound proteins or organelles.



In Constant Systems' equipment, the client sample is fed from the inlet hopper into the high-pressure chamber in 10mL aliquots. Each sample is put under very high pressure (up to 40,000 PSI) instantly and forced through a small, fixed orifice, creating huge shear forces. The sample accelerates up to 650 m/s as it passes across and through

the orifice and acting pressures on the sample instantly return to ambient. This release of acting pressure breaks open the cells within the sample.

Such rough handling might be expected to damage the cells but in fact, by controlling the pressure very accurately, Constant Systems can ensure that the pressure used is sufficient to break open the cell wall but will cause no damage to the intracellular components that are released, which allows the client to maximise their yields.

Disruptors or homogenizers?

Constant Systems produces equipment specifically dedicated to cell disruption, but many potential clients currently use relatively simple homogenizers instead. Without control, the pressure exerted on each cell by homogenizers can fluctuate, leading to inconsistency and low reproducibility with sample processing

Developing such cutting-edge equipment was not achieved overnight. Constant Systems was founded in 1989 by John Harbidge who identified a requirement for an automated alternative to the then-ubiquitous French Press. Setting up in a barn near his cottage in Beausale, Warwickshire, John employed a team of five and quickly found markets worldwide.

Current MD, Richard Mallabar, who qualified as a Toolmaker, was recruited in November 1996 to manufacture the engineering components within the equipment. Richard's dedication to using first class tooling, materials, engineering and assembly methods was instrumental in creating the refined product the company offers today.

Richard remembers his first week fondly, mid-November in a barn, wearing multiple layers with only a token Calor gas heater... Having fought through his first week, Richard saw the company slowly grow under the stewardship of John until 2001 when it was acquired by the Score Group, a Scottish supplier of valves for the oil and gas industry. The fit was not perfect and looking back Richard is clear that the acquisition was a pet project of the then Chairman, Charles Ritchie. Having been through a couple of management teams in 2010 the Score Group directors felt they had to make another change, having



previously promoted Richard through team leader roles and then head of production, they asked him to take the reins and the MD role.

Having identified and eradicated many of the quality issues in the nine years under Score Group management, Richard turned his attention to capitalising on past sales. “In that period our name was certainly well known, although perhaps not for all the right reasons, but we had a good penetration of the academic markets. This has really been good for us, as students are always moving, and they take their knowledge of your equipment with them. Visiting students and researchers get access to your equipment and those studying abroad want to have the same quality approach when they return home. So, word of mouth has, over time, become our friend. At one stage our sales were 80% into academia but we are seeing a greater take up in industry as the academics move out into the big wide world.”

“We never build or install a problem. We buy our components carefully, we have great relationships with our supply chain, we manufacture and assemble to very high standards and we have an excellent engineering team who know what is expected of them. Importantly, this is the same team who install and service the equipment and also train the users, so they can emphasise the essentials of keeping the equipment in tip-top condition, through correct usage and importantly correct cleaning. This enables us to spot any issues early on and have them resolved. We never just leave the handbook with the client and go! Over recent years we now see our warranty costs around 0.1% of turnover”.



“Our engineers have a brilliant reputation and the vast majority of our testimonials mention our service. I qualified as a toolmaker, but I’ve had to learn a lot about servicing clients over the years and it’s a myth that the client is always right, you have to listen to the client - that’s very important -but more important still is understanding - and this sometimes takes us down the path of guiding the client to something they hadn’t previously considered or known. This way we provide what they actually need, rather than what they ask for. The client consultation is a very important process where we explain what we are doing and highlight the differences. That way we ensure they are happy with the results.”

Constant Systems was acquired again in 2021, this time by the Crompton Group. Crompton does not own any other lab companies, it specialises in manufacturing, electrical control supplies and rotational moulding. ARX are also part of the group – an anti-piracy company, not engaged in IT but in the old-school prevention of boarding of vessels at sea. John Bradley who leads the Crompton family as Chairman, has the passion, experience and support to assist in growing Constant Systems and this has been apparent since the acquisition.

So, what’s next? “In the past we have struggled to allocate as much time to R & D as we would have liked, and recently we’ve added to our engineering team to not only increase our build and service

capacity, but also so we can allocate more resource to R&D. We are growing the scale of the equipment as greater and greater throughput is required. Our next iteration will be able to process up to 150L per hour for a client who wants to produce 3000L per week.

“We do not do this alone.....over the last two years we have dedicated a lot of time and resources to our distribution network and we have on boarded and trained nine additional distributors in the last 12 months. We ensure that all our distributor partners have the same access to documentation whether it be technical, sales, marketing or aftermarket support. The distributor has real time access wherever they are in the world removing the reliance on the UK office being open. This saves the distributor time and also gives confidence to the client as more of the client questions and queries can be answered in real time. It took an immense amount of time and effort to create this cloud platform and train the distributor network on how to access and navigate the platform, but we realise the long terms benefits are greater when the distributor can provide confidence through an improved and quicker service. We also recognise that training for the distributor network is a continuous process, and efforts will always be in place to support them. Critically important is being able to provide our team of distributors a road map to find new opportunities where access to all the cloud-based support system can be implemented in serving customers in their territories.”

Richard is also looking at accessing the more difficult to reach CapEx. “As capital spend is getting harder to obtain, we are finding that our ‘loan to own’ leasing option is becoming more popular. This helps clients to spread the costs into the most convenient financial year.”

The company will be expanding in other ways too: “Now that we are sure of the quality of our current cell disruption lines, we can start to look at expanding our range, probably by acquisition. Other smaller benchtop techniques such as chemical lysis, sonication and bead beating are in our sights.

“One of the reasons I was keen to join GAMBICA was for the networking. As previously mentioned, we have expanded our network recently and we now have a presence in 30 territories and so I am hoping to learn from other members about their distributor networks and what works in different markets. I’m finding some distributors can take a long time to get on board, maybe others will have some tips for me. It’s important to maintain our great level of after-market support, so I am keen to find out how others are managing their support. It will be great to meet like-minded people with the same problems and hopefully, some solutions. I am keen to learn how the rest of the world operates!

Richard’s long-term goal is to achieve dominance in the US market. “Now we are ready to grow sales substantially, so we are looking at taking on new distributors with our main target market now being North America, particularly the US. We want to ensure that we provide the US client with the same level of service that we provide to other territories so we are looking for specialist distributors in the US for equipment sales and over time maybe some of the servicing and aftermarket support - if they can meet our standards of course!”

“Currently, our main competitors in the homogeniser markets are Microfluidics based in Boston, Bee International which is also a US company and Stanstead Fluid Power based in the UK. We would be interested to understand what proportion of the market we currently have, but good data on that is extremely hard to come by!”

Richard will be at the conference in March so do come and say hello to him there!
