



IBO

Strategic Information for the
Life Science and Analytical
Instrument Industry

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Fall 2018 Business Climate Review: Positivity Despite Uncertainties

For the fall installment of our Business Climate Review, **IBO** spoke with representatives from analytical instrument industry trade organizations around the world to learn from their general impressions of the current state of the analytical testing industry and the trends affecting the industry. Discussing issues such as Brexit, diagnostic markets and the M&A environment, the representatives provided a generally optimistic outlook for the industry for the coming year, despite the many economic uncertainties and changes taking place around the world.

IBO spoke with Francis Pithon, vice chairman of **EUROM II**, the Optical and Laboratory Technology division of the European Federation of Precision Mechanical and Optical Industries, and vice president of **Fabrilabo**, a French alliance between lab suppliers and purchasers; **Mathis Kuczejda**, president of Analytical and Laboratory Technologies at **SPECTARIS**, a German industry association representing medical, optical analytical, biological, laboratory, and ophthalmic technology companies and of German instrument suppliers, and president of instrument provider Schmidt+Haensch; **Mike Bähren**, head of Economics and Statistics at SPECTARIS; **Takeshi Kawamoto**, chairman of the International Affairs Committee at the **Japan Analytical Instruments Manufacturers'**

Association (JAIMA); Tim Collins, director of the Laboratory Technology Sector at **GAMBICA**, the UK trade association for instrumentation, control, automation and laboratory technology; and **Mike Duff**, president of US scientific instrument trade group, the **Analytical, Life Science and Diagnostics Association (ALDA)**.

Brexit Looms

All representatives from the global group of instrument trade organizations cited Brexit as a major issue in regards to analytical instrument and lab product sales growth in the coming year. Many uncertainties about the way in which the Brexit deal will pan out, such as a lack of a soft exit and border delays, remain. Speaking for UK-based companies, Mr. Collins indicated, “Some [companies] are already seeing the beginnings of a slowdown/delay in expenditure, which is likely to continue to impact next year, especially for larger-ticket items. The sales pipeline in most areas is good, but no one is committing to orders.”

Additionally, UK government funding initiatives regarding replacement money for EU research are “too vague,” said Mr. Collins. “This is affecting the scientific community with regards to future expenditure, and some customers are saying that they are not being considered as participants by other EU organizations,” he explained. Discussing his views on the possible impact of Brexit on French instrument and lab product companies, Mr. Pithon agreed. Free trade has simplified importing products across Europe, he noted, but with Brexit, this will likely be made more difficult. “If the UK leaves, afterwards, you will have to [complete] more paperwork concerning trade with the UK,” said Mr. Pithon. “Paperwork means time, money and price increases.”

“[Post-Brexit], the impact of the UK on standardization will be much smaller.”

Compliance may also be a pressing issue for instrument companies operating in the UK post Brexit, especially in regards to a specific product receiving internationally recognizable compliance designations. “Because of the big compromise made in order to introduce a European directive (for example, the Pressure Equipment Directive), there is the possibility that we may not be able to CE mark using the British equipment standard as some do now,” explained Mr. Collins. “Will UK companies be able to use different countries’ standards without manufacturing in that country? Will stating [British Standards’] standards internationally carry the weight that it did 20 or more years ago? Unless there is some clarity over the very immediate future, this may prove to be a very difficult area.”

Mr. Pithon echoed these sentiments. “A product sold in Europe must be CE marked for quality, which is recognized worldwide, [and] as part of the EU, Britain had a big influence on any European standards, such as CEN [European Committee for Standardization] standards,” he noted. “But after

a ‘hard Brexit,’ Britain could perhaps leave the CEN organization and only attend ISO committees, where its weight will be less, as bigger countries (USA, India, China) are involved,” he continued. “The impact of the UK on standardization will be much smaller. This is true for many other international organizations.”

Trade Turbulence and Economic Doubts

China was also mentioned by the trade organization representatives as having a potentially uncertain effect on analytical instrument and lab product sales growth in the coming year, primarily in regards to Chinese competition and the trade friction between China and the US. In regards to ALDA members, Mr. Duff said, “Many companies are concerned how the trade dispute between the US and China will play out, the potential implications for the global markets and what international-focused companies can do to maintain their Chinese business in this environment.” Economic issues growth is also of concern to US instrument makers. “The US economy is currently in its 9th year of expansion and many economists and CFOs expect a recession to occur within the next 2–3 years,” he continued. “The US federal government’s debt is now in the \$21 trillion range with a \$780 billion budget deficit estimated for FY 2018, 17% higher than last year.”

“Nowadays, data management is about turning data into information.”

On the other side of the globe, Japanese instrument suppliers are also concerned about macroeconomic factors. Mr. Kawamoto echoed economic issues as a possible hindrance to instrument and lab product sales in the coming year. “Economic recession [is a factor], not only [between China and the US], but also in Asia, Europe and anywhere else that may be affected by the protectionist movement taking place in the US,” he said. “In addition, given the rising trend in long-term interest rates in the US, the future of developing economies, such as those in Asia and Central and South America, are also a concern.”

Likewise, German analytical instrument and lab product companies are also concerned about US-Chinese tensions. “The US and the Chinese market are the most important sales areas, accounting for 14% and 11%, respectively, of total German exports. The growing trade conflict between these two countries could result in a declining demand and an unfavorable development of the global economy,” explained Mr. Kuchejda and Mr. Bähren. The impact of trade issues has already been experience by some German companies, according to them. “A first impression of the impact of trade barriers on business we actually witness in Iran: in the first half year of 2018, German exports collapsed by 41%. We anticipate a similar development for Russia.” Mr. Collins agreed about the

negative effects of US and China's trade dispute. "Business in the US is also suffering from uncertainty because of current US trade policy decisions. There is possibly an element of this in other parts of the world."

In addition to the economic environment, regulatory compliance is also affecting lab instrument suppliers. Mr. Kucejda and Mr. Bähren cited the increasing number of regulatory requirements around the world (such as RoHS, REACH, IVDD, California Proposition 65 [the Safe Drinking Water and Toxic Enforcement Act], F-gas regulation [the EU's regulation limiting use of fluorinated greenhouse gases], etc.) as a hindrance for small- and medium-sized companies, as proper implementation requires "time, manpower and results in decreased productivity." In the UK, Mr. Collins stated that there are also some concerns for companies that need to implement the EU's new IVD Medical Device regulations and the related costs.

Digitization and AI: A Coming Revolution?

All trade industry group representatives cited AI as a major factor in the digital transformation of labs. A key question, though, is finding the best ways to implement big data and AI into company offerings. Companies in Japan are working to find the best methods to realize AI in the lab. "Some of our member companies place great expectations on the new markets that will be created by the widespread use of big data and AI," said Mr. Kawamoto. "They are also working on AI analysis of highly diverse information obtained from analytical instruments to be used for such purposes as the evaluation of drug therapies, proposing of new medical treatments and the discovery of new scientific knowledge driven by big data-based visualization," he continued. "Their stance is to continue making active investments and to search out and refine these technologies, while watching how these technologies will structurally impact industries and markets over the mid-to-long term."

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This sentiment is similar in the US, where companies are evaluating the potential future impact of such developments on how customers and vendors each operate. "Like many companies in our industry, the members of ALDA are trying to understand how big data, AI/machine learning, blockchain, IoT, etc. will be used by our customer markets in the future (especially the health care markets), the impact on their research/discovery activities, product development, manufacturing, clinical trials, etc., and the implications for our industry as suppliers of 'tools' and technologies,"

explained Mr. Duff. “Also, what will customers/users need from our members to facilitate their use of AI, blockchain, etc.?”

Similarly, as Mr. Kucejda and Mr. Bähren indicated, because AI is still in its beginning stages, many companies are still studying its development. “AI is not used extensively in the laboratory yet. There are initial projects and the German manufacturers are aware of the new possibilities and potential, but still a lot of work has to be done,” they explained. “Therefore, companies are highly anticipating the results of the AI strategy of the German government, which will be pronounced soon and which could have positive effects on the local R&D activities. It is crucial that within this process, data protection and data security issues are considered.” SPECTARIS has established a working group entitled “Connected Laboratory Devices,” in which the organization is working on a collaborative communication standard based on OPC Unified Architecture, an industrial automation communication protocol, developed by the [OPC Foundation](#).

One reason why digitization is still in its burgeoning stages is the changing landscape of data collection itself. “Nowadays, data management is about turning data into information,” said Mr. Pithon. He noted that AI will change data processing, specifically in the IVD and environmental markets, and that it can be extremely influential in application usage of analytical instruments. “Software is very important,” he continued. As an example, he noted how MS had been mainly used for inorganic analysis, but is now it used for organic analysis, and software was key element in this transition.

“Over the past few years, many members of ALDA have expanded their presence in the diagnostics markets and prioritized investments in diagnostics companies, and this trend is expected to continue.”

The possible effects of such changes may be especially evident in certain markets. As Mr. Collins indicated, a major sector that will implement AI is the diagnostic market. “Health care markets are going to benefit the most from AI, big data and sensors,” he said. “Pharmaceutical companies will still be a source of new drugs/supplements and ongoing business, but the services side of well-being and online diagnostics by apps, computers, etc. will help customers take preventative action and drive more health-related activities. This could provide growth in sectors addressing the consumer health markets.”

Sights Set on Diagnostics Market

These consumer health markets are also providing opportunities for companies traditionally associated with research and preclinical applications for instruments. With new initiatives taking place in the medical community, companies are moving towards the diagnostics arena to diversify and address the age of personalized medicine. “Over the past few years, many members of ALDA have expanded their presence in the diagnostics markets and prioritized investments in diagnostics companies, and this trend is expected to continue,” explained Mr. Duff.

“From health care focused on treatment, inroads are being made worldwide in prevention, early diagnosis and treatment, and individualized medical care.”

This is true worldwide. “We see great market potential in [diagnostics] because of the growing demand for health care in general, the high speed of technological process which leads to new diagnostic possibilities, and the need for fast and efficient clinical tests to lower health care costs,” said Mr. Kuczejda and Mr. Bähren. “The more diagnostic tools focus on the stated market drivers, the higher their market potential will be. As an example, [take] Raman spectroscopy, which changed more and more to a point-of-care diagnostic tool,” they continued. “Another trend is the possibility of improved anamnesis through supported information systems like the electronic patient file and field analysis.”

In Japan, opportunities abound across many segments within the diagnostics sector, including genomics, pathology and pharmaceuticals. “Genomic panel testing markets are also experiencing a period of dramatic startup in Japan,” said Mr. Kawamoto, pointing to the 11 hub hospitals and 300 medical institutions in Japan that have begun genomic panel testing for early cancer detection. Prevention is a key trend, with companies combining digital capabilities with more traditional diagnostic technologies. “As pathology research markets undergo rapid change in response to advances in digital technologies, diagnostic technologies have in particular become a growth market due to the digital revolution,” explained Mr. Kawamoto. “From health care focused on treatment, inroads are being made worldwide in prevention, early diagnosis and treatment, and individualized medical care.”

Mr. Kawamoto indicated these inroads are converging, such as the accelerated development of breakthrough drugs and diagnostic technologies, as well as the streamlining of pharmaceuticals development. In addition, the effect of regulatory changes is ongoing. “Another trend with potential impact is the regulatory revision of the Medical Care Act and other such laws,” he continued. “With plans in place for legal revisions aimed at such issues as securing the accuracy of genomic testing and chromosome analysis, the response of medical institutions to legal reform is in the spotlight.”

Legal issues within the diagnostic sector were echoed by other members as well. Mr. Duff cited regulatory and reimbursement issues as pressing factors for ALDA members, while Mr. Pithon emphasized the need for greater analysis capabilities with the emergence of personalized medicine. Mr. Pithon also cited the rapid consolidation of IVD labs in France, due to more automated testing, as being a major trend in the diagnostics segment. “Twenty years ago, there were over 5,000 labs in France for IVD testing,” he said. “Now there are less than 1,500.”

The M&A Factor

A major opportunity for analytical instrument and lab product companies is M&A, and most representatives of the instrument trade organizations agree that M&A is likely to continue, driving profitability and encouraging competitiveness. Newly formed companies are also a major factor in M&A, according to Mr. Kucejda and Mr. Bähren. “One relatively new but important element in the business strategy of our members is the cooperation with startups,” they said. “Our companies seek the contact with startups in order to increase innovation, specifically regarding digital solutions. Especially in the analytical and lab sector in Germany, this works out well and benefits both.” SPECTARIS is also providing startup pitches and plans to build a startup network, they added.

Generally speaking, however, Mr. Kucejda and Mr. Bähren emphasized that there are two sides to M&A that are equally important. “Many of our members are well positioned and often hidden champions in their specific segments. Seen from this powerful position, we consider the M&A activities as an opportunity which allows our companies to broaden and strengthen their enterprise,” they explained. “On the other hand, we will have to observe what will happen in the mid-term, if Chinese companies will intensify their efforts to enter the European market and start with strategic acquisitions.”

“Against a background of ‘work-style reform’ currently underway in Japan, industries are seeking ways to improve work efficiency.”

According to Mr. Collins, Brexit is a major factor in delaying acquisition activity, but M&A is still expected to continue, especially with certain small- and medium-enterprises that have healthy revenues. “The market continues to consolidate leaving larger global players displacing smaller local and national businesses,” he explained. “Some SMEs are also relatively rich and are looking for suitable targets.”

Issues on the Horizon

In regards to future opportunities and risks that the instrument trade organization members are concerned about, Amazon was cited as a potential obstacle by both Mr. Collins and Mr. Pithon, specifically its effect on instrument and lab product distribution as well as larger distributors. Mr. Pithon explained that Amazon could provide new opportunities for small- and medium-sized companies looking for more efficient distribution as Amazon is well known for that. “They also master AI—the question is how they will use it.”

Separately, debates around the workplace are affecting companies in Germany and Japan. “In Germany, business is going well and we have full employment. Whereas this is a comfortable situation for the employees, it is a growing problem for the manufacturers,” explained Mr. Kucejda and Mr. Bähren. “The national lack of skilled labor continues to increase and affects every kind of company level. For a small- or medium-sized business which is located outside the main cities, it is nearly impossible to recruit well-qualified employees for an adequate salary. In combination with rising commodity prices, this can seriously limit or even harm the economic development.”

Topics of Interest for Global Instrument & Lab Prod. Trade Org. Members		
New and emerging markets	Electric vehicles and clean fuel	International compliance issues
Skilled workforces	Eco-friendly consumer products	Trade tensions between the US and China
Changes in purchasing processes	Chinese environmental regulations	Impact of elections/new federal government
Government strategies and funding	Industrial and public infrastructure	Stock markets, potential recessions
Amazon's effect on distribution	Diversifying semicon. device applications	Recruitment and retention of HR and staff

In Japan, securing a proper workforce is also on companies’ minds. “In the international expansion of business, developing and procuring human resources capable of working on globally valid solutions to issues [is important],” noted Mr. Kawamoto. But he also commented on how a cultural shift in Japan in perspectives toward work is creating business opportunities. “Against a background of ‘work-style reform’ currently underway in Japan, industries are seeking ways to improve work efficiency,” Mr. Kawamoto said. “Associated with this are trending needs for analytical instrument labor saving and ease of maintenance.”

Efficiency, productivity and new applications continue to be key factors for life science companies, as noted by representatives from analytical instrument and lab product organizations around the world. The outlook for the coming year is positive on the part of these organizations, as they continue to meet the challenges of a rapidly changing world.