Speeding Time to Market

Dr Patricia Lobo of *PMPS* speaks to Colleen Ellis, Director of Strategy, Alliances and Channel Development; Martin Atkinson, Business Manager for Northern Europe, UK and Ireland; and Benjamin Bryant, Leader, Global Marketing Communications at Honeywell's Automated Control Solutions Division – Chemicals, Life Sciences and Consumer Goods

Colleen Ellis is Director of Strategy, Alliances and Channel Development for Honeywell Industrial Solutions' Chemicals, Life Sciences and Consumer Goods Business. She has been with Honeywell for 11 years. Colleen holds an MBA from the American Graduate School of International Management and postgraduate executive programme certificates from Harvard School of Business, Boston University School of Management and Kellogg Graduate School of Management.

Martin Atkinson is Honeywell's Pharmaceutical Business Manager responsible for Northern Europe, UK and Ireland. He has over 17 years of experience within the business process and commercial manufacturing world. Prior to joining Honeywell's team, Martin worked for four years at Intellution, an Emerson company, where he created a proven track record of success in product business development (batch), customer-facing international sales management, channel development and global key account management. Before this, Martin spent five years as a Systems Sales Manager for a system integrator, focusing on large batch and MES opportunities. Prior to this, Martin spent seven years as a production/process Project Manager for a leading global CPG business.

Benjamin Bryant co-ordinates global communications for Honeywell's Chemicals, Life Sciences, and Consumer Goods business, his employer since 2000, when he represented the POMS business exclusively. Prior appointments include service as well-known radio and news presenter in Austin, Texas, and work for the United States Army & Exchange Service in merchandising and promotions. Benjamin is a member of the Association of the United States Army and the Public Relations Society of America, where he serves on the 12-member executive board of the society's international section. He has attended the University of Texas and the business programme at the University of Phoenix.

Q Colleen, perhaps you could start by giving a brief overview of Honeywell?

A Honeywell is a US$25 billion diversified technology and manufacturing leader, providing customers worldwide with aerospace products and services; control technologies for buildings, homes and industry; automotive products; power generation systems; speciality chemicals; fibres; plastics; and electronic and advanced materials. The company is well over 100 years old and operates with 120,000 employees in approximately 95 countries.

Honeywell's Chemicals, Life Sciences and CPG business is a part of Honeywell Industry Solutions, a global business in the Honeywell Automation and Control Solutions (ACS) group, which recently brought together two control systems businesses: Industrial Control and Home and Building Control. This was in the interest of both Honeywell and industries such as the pharmaceutical space, allowing for more aggressive global responsiveness and delivery to our valued customer base.

Q What is the Automation and Control Solutions group and what does its advent mean to the pharmaceutical and biotech manufacturing industries?

A Honeywell ACS provides automation and business solutions that help customers to achieve improved productivity, compliance, safety and decision-making. Automation and Control Solutions in itself is a US$8 billion global leader in providing product and service solutions to create efficient, safe and comfortable environments and to help business and industry improve productivity and profitability. It comprises four businesses: industry solutions; service; security and fire; and control products. Serving the space we are in, ACS provides automation systems, advanced software solutions, and value-added services used in a variety of industries.

Honeywell ACS is one of Honeywell International's four key businesses. It was created by taking the processes and standards of standard operation practices that have been implemented in the process production part of the house and marrying them to the fire and safety and environmental and cleanroom interests of the facilities management. This has formed the new division – Automation and Control Solutions.

Q What does your software do for the pharma and biotech companies, Benjamin?

A Our solutions drive regulatory compliance, simplify new product introductions, optimise batch control and control the environmental ambient conditions of facilities. This integration is part of our unified manufacturing exchange (UMx), which is really an evolution in the traditional collaborative manufacturing thrust we are seeing so much of in the marketplace today.

We continue to conduct research and have had many user forums, including several permanent user advisory boards, that help us to best understand the identification and nuances of the issues that the industries face and translate them directly into our product development.

The key for us is threefold: maintain compliance/reduce risk, accelerate time-to-market, and enable flexible manufacturing.

We also have a number of key partnerships and alliances with complimentary solutions providers and consultancies that make up a comprehensive network of software, technology and consulting partners. Technology and software partners such as Taylor Scheduling and Aegis Analytical make it quite easy to put together as robust and complete an offering portfolio as you will find on the market.

With regards to the development and delivery of our best-in-class software, we have a key relationship with the AAC Consulting Group, which is one of the largest independent providers of regulatory, compliance and validation services. The group primarily comprises actual former FDA officials and has over 39 years' experience in the areas of developing and maintaining regulatory strategies and quality assurance programs. AAC assists with cGMP compliance; regulatory submissions; HACCP

analysis and plan development; and validation of facilities, equipment and computer system and training on all aspects of regulatory compliance. Their expertise is invaluable, and clearly shows in the excellence and competency of our software solutions.

Key software serving these spaces had their European launch at Interphex, including the latest generations of the POMS line flagship solutions, POMS Manufacturing Execution System (MES) v.5.0, POMS Clinical Manufacturing Supplies (CMS) solution v.5.0, and the second generation of POMS eSpec – our breakthrough electronic specification solution. Such aggressive technology enhancement and delivery backs up Honeywell's stated commitment to being at the forefront of technology and innovation in this space.

These, and the sum of Honeywell's products and offerings provide a single source for process automation, production management and environmental control solutions. That's a key differentiator for us as a solutions provider. From Manufacturing Execution System to batch, to additional services such as Honeywell's Enterprise Building Integrator make up what we call Honeywell's Unified Manufacturing Solution, a key part of the new and very exciting Honeywell Experion™ Process Knowledge System (PKS) – forming a comprehensive life sciences solutions portfolio that quite simply enables e-business by addressing the entire product life cycle – from product development through manufacturing and packaging operations.

Q What standards do you use for this software Colleen?

A We comply with ISO 9000, 21 CFR, all of the FDA Regulations such as the critical 21 CFR Part 11 and cGMPs. For our batch solutions, S88 and the later S95 standards are also crucial.

Q Who are your clients for this software?

A Our clients are the global pharmaceutical companies you see in the top 20 of the Fortune 500 list of companies. They are also specialised manufacturers (including food and beverage, consumer goods and cosmetics, all seeking pharmaceutical grade quality guarantees, as well as chemicals manufacturers), and smaller life sciences and contract operations.

So many of our clients are worldwide producers. This is significant in our market space because we are seeing that cost and other factors are driving the pharmaceutical companies that are equipped to market their products globally, bringing along a previously unseen slew of additional requirements and complexities in terms of regulatory compliance, distribution, storage, tracking, labelling, accountability and culture. All of these factors come into play when you are competing on a global basis.

Also, with the trend for longer and larger clinical trials you find the need for increased time to market compression – even one day can have a huge financial impact and so another key requirement of our customers is that the solutions we offer not only have to be globally implementable, based on standards, but they also have to be scalable.

In some ways, it is the global enterprise that defines the requirements of the industry and in doing so, defines the requirements for our own product development.

Q Does that mean you would only work with a very large global company? What about contract manufacturers and small biotechs?

A This is an interesting point, because what we are seeing, particularly in biotech, is that where many of the major pharmaceutical companies used to do their own up-front clinical research, there is now a second tier of companies that have emerged over the years that provide an outsourcing service, and those are targets for our software.

It is very important for us to be clear. While our client base is mostly made up of the large, global players in terms of percentages, Honeywell is just as committed to serving the more specialised manufacturer. We recognise and respect the growth that marks the areas of contract manufacturing and especially biotech. We're in that space when it comes to development, provision of solutions and knowledge and commitment. We see both as growth areas and treat them as such.

In fact, we have been actively working to drive down the costs of implementation and ownership to be more attractive to smaller biotech, pharma and regulated CPG companies, particularly with regards to our POMS line of offerings.

Our experience in successful delivery to each of these areas – on the largest of scopes and in the most specialised of manners is a big differentiator for us. We are a global company, with a comprehensive set of solutions that go from dock-to-stock, and we have experience and a proven track record with all types, sizes and oriented customers. There is no doubt that our experiences at each level and in each area give us particular perspective, skill and expertise. This translates to all of the others, which benefits everyone tremendously.

That's one of the things that set us apart from the competition.

Q With the biotech companies, if you are saying they are outsourcing their manufacturing, which type of biotech company are you looking at Colleen?

A Genzyme or Genentech are examples of the type of company we are speaking of. What we find in many of the pharmaceutical companies is that they are reinventing themselves in genetically altered and genetically influenced environments because of the value in the product itself. On the agricultural side of the house – in the US more so than in the European environment – we are seeing a lot of traditional chemical companies moving into biotech or bioengineering, such as DOW or Elansa.

Q Who in the pharma/biotech industries is most interested in the software?

A It varies because the Honeywell solution set is so diversified that we can approach from an operator effectiveness, abnormal situation management, and collaboration field management perspective, among many others.

The people we broadly speak to are those in operations at a line of business or enterprise level. We speak to plant managers and executives who focus on quality assurance or regulatory affairs because they – more than anyone – know that compliance validation is critical from the corporate level down to the plant level. To our customers, compliance and validation is a management strategy.

Q What are the drivers for this market?

A The top three are: the ability to maintain compliance (thus reducing risk), accelerate time to market, and enable flexible manufacturing. These have been, and will continue to be, drivers in our development process as well. I'd have to say compliance sits at the top because that's where the risk and cost are found. Unlike CPG, there can be no re-work in pharma, work must be re-done at significant cost, FDA fines for lack of compliance, or a drug recall automatically mean crippling costs for a company.

21 CFR Part 11 and cGMP compliance are by far **the** key drivers. The added benefits of product simplification, of time to market, of lower cost, are valued drivers of course, but the key driver that our customers identify, supported by all of our research is compliance.

Q You mentioned collaborative manufacturing – what is it?

A In recent times, industry interest in the concept of 'collaborative manufacturing' has grown. Collaborative manufacturing optimises business performance by removing physical and logistical barriers that have traditionally stood in the way of the entire manufacturing process from decision-making to execution. With fully collaborative manufacturing, a new value chain is created, allowing for data integration and harmonisation of internal and external processes – delivering more value for end-customers and earning increased profitability. The promise of collaborative manufacturing is lower risk and an improved ability to meet customer specifications and delivery schedules, at a lower overall cost to the manufacturer.

Honeywell is deeply committed to the idea of collaborative manufacturing and to delivering the promises of the concept in a focused way to our customer base. In our life sciences business, collaborative manufacturing strategy is embodied in the aforementioned Experion process knowledge system (PKS) and via our unified manufacturing exchange (UMx), which provides the means for companies in the process industries to have real-time co-ordination, visibility and responsiveness across the enterprise – along with tighter collaboration with supply chain partners. This significantly expands the opportunity for manufacturers to turn improved information and workflow into better financial performance.

The elements of collaborative manufacturing are even found at our product level, such as with POMS eSpec, which promotes rapid and consistent hand-over, transformation and exchange of specifications with customers and suppliers – internal or external – through the Internet and internal intranets.

Q How can Honeywell help in the management of clinical trial supplies Benjamin?

A The European launch of our latest, most functionally rich, clinical supplies solutions, POMS clinical manufacturing supplies (CMS), took place at the Interphex UK show. CMS is a fully 21 CFR Part 11 compliant enterprise production management and execution system for the manufacturing, packaging and distribution of clinical supplies. It provides complete traceability from raw materials through all stages of manufacturing and ultimately shipment to the investigator,

including returns. The inventory management and recipe-based, interactive electronic batch record capabilities of the application reduces the cost of compliance while increasing the efficiency of supplying materials for increasingly complex and frequently changing clinical trials. It also easily integrates to existing enterprise systems such as randomisation, LIMS, IVRS, EDMS and ERP.

Version 5.0 which was launched at Interphex, provides best-in-class recipe management with graphical recipe building, intuitive action list builder, and many best practice objects for recipe building and execution. Inventory management tracks receipts through shipments and supports traceability through subcontractors. Production management and execution manages orders, allocates and reserves materials, dispenses materials and enforces the execution of the recipe while recording the electronic batch record.

Q How are you able to help the pharmaceutical companies supply chain in their 'time to market', Martin?

A Every single customer that we are working with is under pressure to bolster their new product pipeline. They want to have more efficient discovery, they want to make sure that as a product moves efficiently through the new drug application process and through to clinical trials, and that those clinical trials are executed smoothly. They want to understand that when a drug is approved for manufacture and is granted a licence, that the actual product is able to be manufactured in the right plant in the most efficient way, with the correct dosage. It is my opinion that is what the pharmaceutical companies want is value in the product cycle chain as you go from discovery to trials, to commercial manufacture. Our customers want to be able to maintain the cost of goods manufactured. That is a simple ratio: cost of manufacture against the sales line.

Pharmaceutical companies want to drive out manufacturing inefficiencies and one of the ways to do that is to ensure that the systems that are implemented are based upon the rapid transfer of process, information and technology, for the platform and knowledge of how that process operates. If I am in a line of business and I have 15 plants that are all geared to manufacture antibiotic products. When I have a new product that is being licensed and I want to manufacture that product, I need to be able to assess all of my assets in my business enterprise and make a decision on where I can manufacture that product in the most cost-effective way to keep my cost of goods down.

If I am a production manager or an operations manager, I am tasked with producing the best quality product to order in the most efficient way. To enable me to do that I need to make sure that my quality affairs and regulatory requirements are met. Whatever system is implemented needs to be deployed to cGMP, needs to comply with 21 CFR Part 11 and needs to assure that there are no validation issues or audit queries. If a customer gets into an FDA audit, the cost of the business can be substantial; a recall can mean hundreds of millions of dollars lost. If you get a 483 warning letter from the FDA, the next time the FDA visits they are going to look at your procedures in exacting detail. The process is never ending.

Q What software would help in this situation?

A The unified manufacturing solution (UMS) which is effectively focused at plant level. It consists of a number of components where it focuses on co-ordination, specification, execution and analysis. It's an ongoing process.

For co-ordination we have a product called eSpec which is an electronic specification management product which enables our customer to assign all attributes or all parameters that constitute the way a product is manufactured, from development to final product.

It then transfers those attributes and parameters for the complete product value chain to commercial manufacturing. It eliminates all the hand-overs between different groups, organisations, that might be in different parts of the world, because it is one electronic system.

Q The UMS system is therefore only cost-effective if the customer is a global player – is that right?

A No. There is greater cost reduction and knowledge transfer benefits in a global company, but that doesn't mean that it is not applicable to a one- or two-plant operation. That is simply a matter of scope. Greater cost equals greater savings.

I think what is important is that whether it is a small or large company manufacturing one product or 50 products, the UMS system eliminates the 'cultural' differences in what exists between different parts of the organisation. It eliminates multiple data points so that you have one data source, one point of entry, one point of visibility for the people who are involved in actually taking that product and saying, 'I know I have a therapeutic product which I think has some benefit to my patient and

I now need to put it into the new drug applications process. While I am going into the new drug applications process and I am starting to look at clinical trials, I still have to take this as compound and I have to manufacture it for my patients'. Basically, what it says is – this is the compound, these are the constituents, the active ingredients that make up the compound, and this is how this compound should be manufactured. It then takes that information into another component in our set.

Q Do you have any systems for materials management?

A We have a manufacturing execution system (MES) that focuses absolutely on commercial manufacturing. The MES looks at materials management from point of receipt of material to the point of despatch and finished goods and all the materials in between. It provides complete tracking and genealogy, down to container level. Additionally, within the MES we have solution set, weighing and dispensing in order to streamline manufacturing operations. We support dispensing in many different forms.

The third component of an MES would be electronic batch instructions. We can really close down on batch automation, drive at the right time levels, so that you know you are really looking at zero error manufacturing. But with MES, the system is transaction-based. It actually produces a complete electronic batch record of all the transactions that go up to making the product that is being delivered to your customer.

It completely satisfies all the FDA and regulatory audit requirements built in. That would be a huge difference between a Honeywell and an EAP vendor trying to take their solution set into the GMP operations space and having to create a validation master plan for that. With us our whole work ethic, our whole delivery mechanism is geared towards the fact that those validation tools are built-in.

Q Over 50 per cent of the contract manufacturing organisations (CMOs) are small companies with one site. Will your systems be useful to help the efficiency of their plants and if yes, will it be expensive for them to buy and set up your systems?

A I think it is an interesting point and I can give you the case study of a small company called Dompé. I think they have two sites in the same place in Laquila in Italy. They have got the Honeywell MES running. One of the main drivers for them to install the system is that it is modular and scalable. The main driver for them uses it as if they were trying to attract the global manufacturers who outsource their manufacturing to them. By having Honeywell MES installed, Dompé can say 'We are 21 CFR Part 11 and cGMP compliant, we are complying with MCA regulations, we have a best-in-class MES to back it all up, and we are able work with the global players'. And that is exactly what they have done.

MES and CMS are sold in a modular manner. This allows the customer to identify their immediate needs, such as a bottleneck in weigh dispense, or a foreseeable validation issue in tracking, for example, and eliminate them through faster implementation and lower, modular, cost-of-entry. This dovetails very closely with the point Benjamin made earlier about making Honeywell's solutions more available to the smaller – but growing – biotechs, contract manufacturers, and so on. By going in at a cheaper cost of entry, with a quicker return on investment, these companies benefit without having to make the major investments regularly made in Honeywell by our global customers. When the results roll in, often in a matter of months, the next step is to identify secondary bottlenecks, often using the cash savings accrued in that first step, and purchase the next module or modules. It's a key example of how we've listened to the industries' needs and delivered real technology in turn.

Q Have Dompé made any savings?

A They have increased throughput, the cost of compliance, and they now have increased capacity. They have a paperless environment so every record they produce is transaction-based on a transaction by the Honeywell MES. They are attracting significant new business as a contract manufacturing organisation from the global players because they have a Honeywell MES.

By definition, global players either have a Honeywell MES installed or they would have evaluated the Honeywell MES and can assess that for themselves. As a contract manufacturing organisation they have invested in their business and their infrastructure to enable manufacture of a product. They now have the infrastructure in place to back up their claims. ◆

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