New Environments

The Internet of Things impacts many sectors, especially pharma manufacturing. Specifically, the integration of digital technologies is influencing regulatory compliance and industry standards

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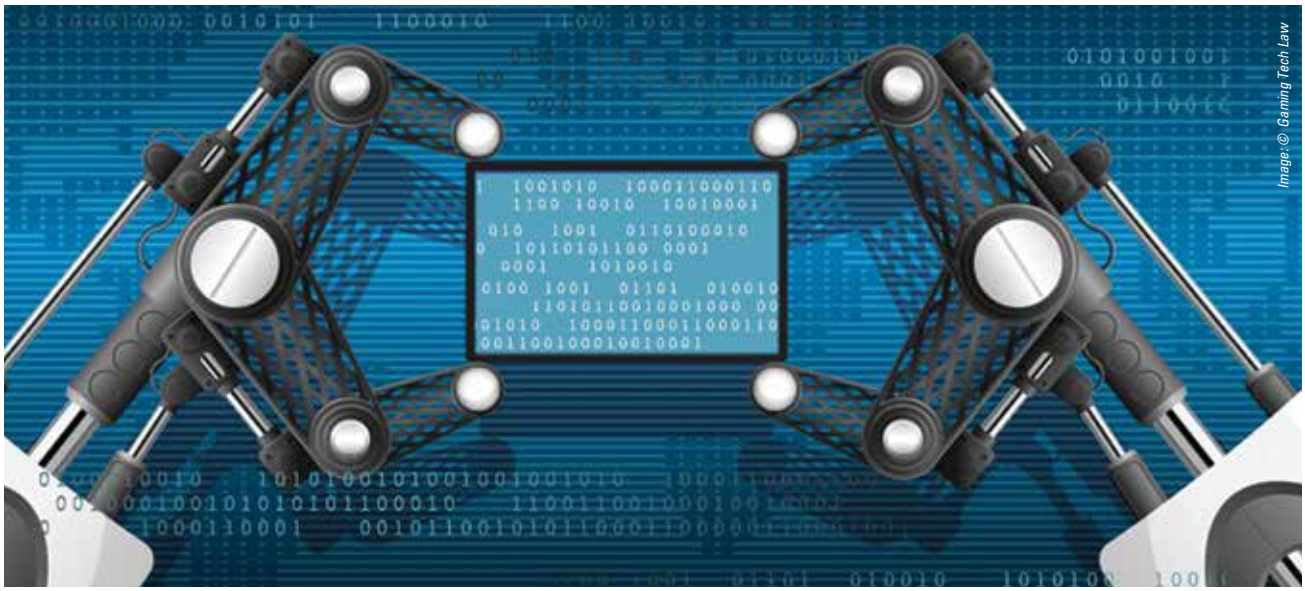
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Current biologic, pharmaceutical and emerging personalised medicine development environments are rapidly evolving. Production processes, including single-use, continuous and new therapy modalities, are driving commercial operations to evolve quickly to keep pace. Strategic partners are working to integrate key technologies, allowing stakeholders to realise the promise of Industry 4.0.

The pharma sector has always been challenged to swiftly innovate while staying within regulatory compliance boundaries. Inside product development and clinical or commercial manufacturing disciplines, this field is again being asked to acquire, contextualise and deliver data from sources in ways once thought too expensive or technically challenging to achieve.

The future of the Industrial Internet of Things (IIoT) is extremely promising, with an estimated potential benefit of $1 trillion. This kind of figure is astounding, but how can manufacturers get started with capturing some of this value? Rather than looking to revolutionise business by transforming the entire infrastructure model, many companies are seeing results by starting small and focusing on specific problems that have been difficult to solve with existing methods. Leveraging technologies currently in use has allowed organisations to begin delivering quality.

IIoT technology automates the once-problematic practice of collecting valuable information from critical process equipment and also facilitates integration to analytical systems, delivering data to experts who derive actionable insights. Its fundamental enabler is to connect the unconnected. In the last paradigm, countless process and machinery variables were not measured or, worse, they were calculated, but were abandoned due to physical safety or practical barriers. Innovative sensing combined with secure linking allows for the aggregation of information that was previously lost because it was either not determined or the data was trapped in isolated legacy systems.

Regulatory Compliance

Data integrity has been around since the 1990s and may well be the phrase of the century in some regulatory circles. Its increasing focus and awareness in all aspects of a molecule's lifecycle has driven the need for diligence – from the laboratory to packaging. The Good Documentation Practice-issued acronym attributable, legible, contemporaneous, original and accurate (ALCOA), as well as ALCOA+, can test a human's limits. However, IIoT monitoring networks can deliver significant benefits by automating data collection that was previously done manually. Not only does this free up resources, it provides stronger compliance between the source and the permanent digital record.

New sensing technologies are being introduced for application areas that are a good fit for reliability and performance monitoring cases. The traditional paradigm for instrumenting a process is based on calculating the variables required to control and operate machinery. Measurements necessary for

monitoring applications are often left untouched, with the expectation that manual ones will be taken to diagnose and troubleshoot problems when they occur. This model requires an expert to be present, leads to inaccurate calculations and is more reactive than predictive.

New wireless sensors, such as acoustic, vibration, power, temperature and pressure transmitters, are available, offering greater flexibility and lower costs. These are installed on monitoring solutions for motors, valves and heat exchangers, as well as other critical equipment, and are commonly used for observing health and condition, enabling more proactive and predictive maintenance. By deploying these networks separately from the traditional systems, the design specifications can be simplified and the data integrity and regulatory compliance requirements are reduced.

The New Normal

Control of all data from one centralised location or team has become very challenging. Over the last 10 years, biologics and pharma manufacturing stakeholders have gone to great lengths to leverage technology while designing flexibility and smaller capacities into facilities. This has been made feasible through internal industry improvements to production titre, therapy efficacy and single-use. External drivers such as local governments promoting 'in-country-for-country' development, expanded 'Western' medicine adoption, tax incentives and population growths have contributed to dispersion worldwide.

Additionally, with the emergence of personalised medicine, manufacturing is being miniaturised in ways once only imagined in science fiction. How we connect with the distributed systems and production areas requires careful consideration and planning. This integration of methods, locations and data formats is dramatically impacting the complexity of acquiring and contextualising information, as well as network coordination.

Considering the recent Peyta and NotPeyta attacks, data, their networks and infrastructure must be thoughtfully designed and developed. While the IIoT is solving many challenges, it has introduced a degree of business risk due to potential protection vulnerabilities, compared to traditional, non-computerised systems. To get data into analytics and expert hands, safe connectivity is required. No 'one-size-fits-all' approach exists that has flexible options necessary for different scenarios. Security is an important requirement for connectivity, adding an additional layer of complexity.

Often, stakeholders are asked to make challenging decisions to balance base functionality, capital budgets and tight project schedules or to mitigate validation expenses, producing growing islands of automation and stranded data. The once-distant promise of Industry 4.0 and the IIoT are now providing solutions that capture abandoned information and deliver results through actionable insights, serving to improve operational performance and reliability.

Valuable data are already available in existing automation software, and many companies have deployed complex historian processes to aggregate time series information from control systems. Additionally, new wired and wireless field gateways are collecting new measurements that can be combined with the latter's sources to create a rich environment for analytical applications, such as machinery health and performance monitoring. This will continue to be a very effective approach for consolidating process and equipment data across the various systems that are deployed in operations, and many IIoT success stories are based on this.

New software connectivity is enabling the enterprise-level data historians to integrate with cloud services for more advanced storage, visualisations and analytics. In other cases, edge gateways are being used to join sensor networks and control systems more directly to the cloud. The role of this is to collect information via industrial protocols – Open Platform Communication, Modbus and Highway Addressable Remote Transducer – and to convert the information into new IIoT ones – Advanced Message Queuing Protocol and Message Queue Telemetry Transport. These often include message filtering and buffering capabilities, and, in some cases, they can host algorithms, rules and light-weight analytics applications. Lots of new hardware and software innovation is happening in this space, causing confusion for end users deciding which option to choose.

Cloud Computing

The cloud has become the solution for many technology-related challenges. The industry is yet to overcome some functional, practical and psychological boundaries, but real quality propositions exist for many applications that reside in the cloud. Rapid scale-up of repeatable infrastructure items without physical constraints and low total operating costs are often value enough, but what does cloud computing mean and what can the industry do today?

Cloud computing has many different meanings, and the advantages can be a little 'cloudy' without the right approach. In the context of IIoT, it provides a highly scalable, cost-effective and centralised computing environment with sufficient power for data ingestion, aggregated storage, advanced analytics and visualisation. The latest developments in this provide highly functional services integrated into customised platforms that are built for IIoT solutions. Rather than hosting virtual machines in Infrastructure-as-a-Service environments, cloud vendors are developing feature-rich Platform-as-a-Service offerings that enable rapid development, deployment and enhancement of Internet of Things services.

Integrated with these cloud-based platforms are powerful analytics technologies that can be used by data scientists and domain experts for information mining, modelling

and development of new algorithms that can be deployed into applications for process monitoring and optimisation. Cloud services can initially serve to put data into the hands of professionals so that they can detect problems. In today's world where expertise is becoming harder to find and has significant limits to scalability, advanced analytics can embed this into model-based applications that direct professionals to the area of focus. These new systems can further improve the scalability of competency by automating anomaly detection, diagnostics, prognostics and decision-making.

What About Tomorrow?

One can easily debate whether the IIot or the life sciences manufacturing environment is evolving more rapidly. Changes can create a sense of uncertainty and doubt regarding the timing of IIoT solution adoption and deployment. If one is looking for help solving challenges with regulatory compliance, connecting to distributed assets or breaking free from traditional computing technology, solutions are available. While tomorrow promises more innovation, the potential for improvement exists today.

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