By leveraging connected systems, data and analytics, Life Sciences companies can further reduce costs and increase safety, efficiency, and revenue. More importantly, companies can accelerate business transformation efforts in the face of new and increasing market challenges.
Introduction
Pharmaceutical manufacturers are facing an ever-present need to remain competitive in a marketplace where product portfolios are diversifying, innovative start-ups are challenging the status-quo, supply chain partners are becoming more integrated and patients more involved in decisions around their care.

To gain a commercial edge, Life Sciences manufacturers must continue to embrace Manufacturing 4.0’s new tools and processes that enable smart, decentralized production while building on the Life Sciences industry’s strong legacy in data collection. Right now, almost every device in a GMP manufacturing facility collects data and the industry continues to complete projects to physically connect all these devices and systems. As such, radical changes in the Life Sciences industry does not need to be driven by radical investment but by ‘making the most of now’.

With intelligent factories, integrated IT systems, the IoT and flexible, highly integrated and automated manufacturing systems, the Life Sciences industry can enhance the ways it already collects, visualizes and analyses data. Beyond improving the performance of the manufacturing supply chain, better data could help deliver new products and services that are cheaper, faster, safer and of higher quality than they were before.

Optimizing your digital technology and data
Manufacturing Execution Systems (MES) and Automation in the Life Sciences industry was set out to deliver incremental (sometimes significant) improvements in efficiency, quality, reliability and safety. With Manufacturing 4.0 they can effectively eliminate human error and delay from manufacturing — preventing waste and upping efficiency, which results in significant financial benefits.

Manufacturing 4.0 holds huge potential for automation with individual management processes throughout manufacturing expected to become automated. Other examples include machine learning algorithms that can adjust manufacturing lines and production scheduling much more quickly compared with human intervention and predictive maintenance capabilities which identifies and corrects issues before they happen. Such developments will create a significant impact when scaled across an entire factory or at the enterprise level.

MES systems enable more meaningful business insight and better usage of resources. For example, instead of just measuring the downtime of a piece of equipment for overall equipment effectiveness, MES can provide batch, cleaning, maintenance and operator inputs as context for the downtime to allow for detailed trend analysis and precise preventative measures to be put in place. Beyond this, increasingly sophisticated and more connected MES systems will revolutionize production both in single plants and across global facilities as better approaches to recording and accessing data in real-time are adopted.

Appetite for change: Embracing Manufacturing 4.0 in Life Sciences
In 2018, Zenith Technologies, a Cognizant company, conducted a survey of business and operational leaders from across the Life Sciences sector. 58% of respondents said that Manufacturing 4.0 will drive the most change over the next five years — more than any other technology area. When asked their motivation for investing in new technology:

<table>
<thead>
<tr>
<th>Motivation</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wanted to save money in manufacturing processes</td>
<td>77%</td>
</tr>
<tr>
<td>Wanted to save time and increase efficiencies</td>
<td>69%</td>
</tr>
<tr>
<td>Wanted to increase revenue</td>
<td>62%</td>
</tr>
<tr>
<td>Wanted to understand patients better</td>
<td>19%</td>
</tr>
</tbody>
</table>

While the criteria that drives decision making and investment in the Life Sciences industry remains the same, a new mindset has developed. The traditional approach in pharma manufacturing with regards to investing in new technology has been to identify the need and opportunity, procure, install and validate. However, with Manufacturing 4.0, change will be driven by people interpreting data and reshaping the approach in manufacturing as:

<table>
<thead>
<tr>
<th>Investment Area</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will invest in people to make more of emerging technologies</td>
<td>77%</td>
</tr>
<tr>
<td>Will improve legacy systems</td>
<td>46%</td>
</tr>
<tr>
<td>Will leverage third-party support</td>
<td>46%</td>
</tr>
<tr>
<td>Will invest in new systems</td>
<td>42%</td>
</tr>
</tbody>
</table>
Connect everything and create context

The foundation of any change to a manufacturing environment driven by Manufacturing 4.0 thinking will be contextualized data and connectivity.

Every system and piece of equipment needs to be able to record and distribute reliable event data, communicate with other systems and pieces of equipment and subsequently access relevant and reliable data.

Once this connectivity is in place, operational teams have the basis for making better choices, or have the need to make choices removed as self-learning systems do this by interpreting data. In this regard, the implementation of communication standards is crucial as machines and systems communicate directly with each other and make decisions with less human involvement in future.

While the Life Sciences industry has been doing big data analysis for over 20 years, leveraging a Manufacturing 4.0 approach will result in even larger data sets due to numerous variables and data points. This can be very problematic and detrimental, so it is vital that businesses adopt the data-driven improvement cycle approach — DMAIC:

Define Measure Analyze Improve Control

The only correlations that should be acted upon must be carefully hypothesised, tested and validated. Process engineers must measure a large amount of data with a small number of variables, wait, monitor and define improvements before implementing change and starting the cycle again. This iterative approach will only be successful if complete, contextualised and accurate data is collected from a fully integrated network of systems, machines and technologies such as:

- **Data Lakes**
- **Edge Devices / Edge Computing**
- **Machine Learning & Digital Twin**
- **Asset Performance & Utilization**
- **Industrial Apps**

The future of production

The Life Sciences industry has been slower to adopt cutting-edge technologies than other sectors. However, it has spent decades using data to drive operational improvement. Embracing the potential of Manufacturing 4.0 is going to be critical to future operations of all manufacturers as fully automated and connected facilities that can create, interpret and act upon reliable data will take advantage of all that digital manufacturing has to offer.

Our role in the Manufacturing 4.0 revolution is to help manufacturers connect their systems and equipment as well as ingest and analyze the data created. We achieve this by delivering end-to-end smart factory capabilities that enable more insightful data-driven decision-making, maximum operational efficiency and regulatory compliance. This intelligent, integrated and big-data approach will fundamentally change the way Life Sciences manufacturers operate — by implementing digital technologies, they can achieve more successful development and production of life changing drugs and medical devices for patients who need them most.

The Authors

**Ryan McInerney**
MES Project Manager & Technical Consultant

Ryan leads the project implementation and delivery of site services at one of the top 10 pharmaceutical companies in addition to consulting with pharma companies worldwide on MES, Historian and IT implementations.

He has over 9 years of experience supporting four out of the top 10 pharma companies in Operations, MES and Process Engineering, and knows the data analysis techniques and evidence-based decision methodologies that are being deployed right now in the industry.

**David Staunton**
Global Services Director

David leads the delivery of Automation, MES and Digital services out of Zenith’s 16 offices globally. He has over 20 years of experience in delivering such projects for some of the world’s largest pharmaceutical companies.

David also lectures in Project Management on Master’s programmes at University College Dublin and regularly presents at national and international conferences.

About Zenith Technologies

Zenith Technologies — a Cognizant company — is a global enterprise specializing in full lifecycle automation, manufacturing and operational support solutions for the life science industry. Zenith Technologies operates out of 16 global locations and in proximity to all the major life science manufacturing centers. For more information, visit www.zenithtechnologies.com

About Cognizant

Cognizant (Nasdaq-100: CTSH) is one of the world’s leading professional services companies, transforming clients’ business, operating and technology models for the digital era. Our unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient businesses. Headquartered in the U.S., Cognizant is ranked 194 on the Fortune 500 and is consistently listed among the most admired companies in the world. Learn how Cognizant helps clients lead with digital at www.cognizant.com or follow us @Cognizant.