Today's biopharmaceutical industry is undergoing a remarkable transformation as technological innovations ignite a new era in medicine. Allogeneic and autologous biopharma manufacturing and smart cell therapy manufacturing are exciting examples of what is possible with today's cutting-edge technology. Now able to deliver personalized medicine, these advancements have become a vital means for treating a wide range of chronic conditions in clinical practice. Biologics and cell therapies offer another example of the future of medicine, offering the potential to reprogram the way our bodies fight disease.

As the number of personalized medicines and first-in-class treatments continues to grow, the biopharma manufacturing industry has an opportunity to leverage digital transformation to fully capture this new opportunity. Personalized medicine brings with it manufacturing challenges related to decreased batch size and rising costs. Drug development pipelines contain several times more new therapies compared to the number that are currently on the market. Timelines to bring a new biologic product to market are around 18 to 24 months on average. To keep up with demand, manufacturers must achieve higher throughput, yield, and efficiency. Digitization and IT modernization help meet these new demands through improved process controls and streamlined operations.

Intel® hardware and software solutions have been at the forefront of helping manufacturing industries worldwide digitally transform. These solutions can be found broadly across the manufacturing environment and biopharma manufacturing is no exception (see Figure 1).

The technologies serve as the foundation for a move toward modern, software-defined, data-driven operations broadly referred to as Industry 4.0. Just as other industries have, biopharma manufacturing organizations can leverage their investments in Intel-based solutions to advance digital transformation and realize the benefits of Industry 4.0 in the coming years.

Intel has been undergoing its own journey toward Industry 4.0 with a future vision of lights-out operations (i.e., the management of a remote recovery data center through the use of remote management software). Starting with connecting distributed devices for remote control and monitoring, Intel moved to making devices smart by developing autonomous functionalities and analytic capabilities through scalable and agile service-oriented architectures.

Recently, Intel has been incorporating AI and software-defined infrastructure at scale to support greater automation and real-time processes. The results have been impactful. Through use of automation and smart systems, Intel demonstrated the ability to bring a new factory online in just 22 weeks, a time reduction of 80 percent. AI algorithms process more than 5 billion data points per day, allowing engineers to extract key information in 30 seconds instead of 3 hours. And through the Industry 4.0 journey, Intel has increased production speeds by over 3x and headcount efficiencies by over 4x.

**FIGURE 1:** Intel® technologies in biopharmaceutical manufacturing

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**Upstream processes**

- Bioreactors
- Disaster recovery servers
- In-line monitoring (future)
- Analytical instruments
- Computer vision and AI

**Downstream processes**

- Separation and purification
- Chromatography workstations
- Fill and finish
- Automated instruments

**Horizontal systems**

- Distributed control systems
  - SCADA
  - Manufacturing execution systems
- QA/QC labs
  - Cell imaging
  - Chromatography workstations
  - Spectrometry workstations
- Data center
  - Applications
  - Analytics
  - Edge computing

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Business Brief
Biopharmaceutical Manufacturing

Accelerating the Digital Transformation of Biopharmaceutical Manufacturing

How Intel® technologies can enhance efficiency and flexibility on the path to Industry 4.0
Intel helps lead the digital transformation of today’s factory

Also commonly called smart manufacturing, Industry 4.0 refers to the digital transformation of traditional manufacturing and industrial practices. It incorporates technologies such as Industrial Internet of Things (IIoT) devices, software-defined infrastructure, advanced analytics, and artificial intelligence (AI) to establish a more flexible, interoperable, and real-time digital manufacturing platform.

Learn more about Intel and Industry 4.0 in manufacturing at intel.com/manufacturing

Lowering IT costs with workload consolidation

Workload consolidation unites multiple computerized operations onto fewer platforms, replacing separate purpose-built hardware machines with a smaller foundation of general-purpose compute technologies. Reducing hardware infrastructure and using more existing resources helps optimize operations. Such an approach to IT and industrial automation can reduce capital expenses (CapEx) and increase efficiencies and simplify operations to reduce operational expenses (OpEx).

Virtualization is a key technology to support workload consolidation. It allows for the abstraction of software from dedicated hardware and supports total isolation of applications, which is important in a manufacturing setting. Intel® processors include a variety of technologies that enable virtualization of CPU, memory, and I/O. As a foundation to virtualization in the manufacturing environment, Intel processors are rated for a variety of industrial use conditions, and deliver 24/7 dependability, long-life support, and hardware-enhanced security features like full data encryption.

Moving beyond single servers, software-defined infrastructure can provide additional flexibility at the datacenter level. Adoption of a scalable, software-defined platform to support Intel factory automation was found to provide an improvement to key workloads. Results include a 14 percent reduction in defect analysis and support for a better disaster recovery posture with 2x faster restoration of SQL databases. This type of platform provides organizations a head start in their Industry 4.0 journey.

Enabling advanced analytics unlocks new intelligence in data

Biopharmaceutical manufacturers recognize the urgency to extract new insights from their siloed data. It starts with connectivity, which offers process control and productivity gains. It is also a prerequisite to implementing cutting-edge technologies such as real-time release testing (RTRT).

In support of that aim, Intel offers ready-to-deploy software reference designs for image- and time-series data ingestion and advanced analytics, supplementing an organization’s existing information management and control systems (Figure 3).

Managing the challenges and opportunities of AI

The application of AI in manufacturing, while still in a nascent stage, has already created an extensive ecosystem of AI solution providers encompassing use cases such as anomaly detection, computer vision, and predictive analytics. As mentioned earlier, Intel is using AI in its own manufacturing operations, addressing anomaly detection and near real-time engineering insights across billions of data points.

Intel technologies make it possible to run AI models on existing platforms. Such a capability supports a transition to Industry 4.0 by speeding deployment of AI and driving the need for new IT infrastructure investments for AI. With software and toolkits such as the Intel® Distribution of OpenVINO™ toolkit, AI models can be optimized to run on existing CPUs throughout the manufacturing environment. Additionally, the latest-generation Intel® CPUs provide hardware acceleration and integrated graphics to support a wide range of real-time AI workloads.
Charting the path forward for biopharma manufacturing

The biopharmaceutical industry must manufacture next-generation therapeutics that deliver the necessary quality, precision, and cost-effectiveness. Implementing new process-control technologies and improving operational efficiencies are key steps to making the very most of the promise of Industry 4.0.

Intel, a recognized leader in manufacturing and operator of the world’s largest manufacturing sites, supports organizations in their digital transformation. Deep experience, coupled with a broad hardware and software portfolio, positions Intel to help biomanufacturers take the next step toward their factory digitization and IT modernization goals.

Learn more about how Intel technologies are helping biopharma manufacturing chart new avenues of understanding in medicine

Intel® Edge Computing Portfolio: intel.ly/3A7Rg16
Intel® Edge Insights for Industrial: intel.com/edge-insights-industrial
Intel® Edge Controls for Industrial: intel.com/edge-controls-industrial
Intel® oneAPI AI Analytics Toolkit: intel.ly/3hiQ2Yj