The Biopharma 4.0 glossary

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These definitions are based on or influenced by various sources, including documentation from BioPhorum, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), as well as other prominent industry publications.

The Biopharma 4.0 glossary

Term/Abbreviation	Definition	Source
Agile manufacturing	A flexible and adaptable approach to producing personalized drugs and medicine to meet patient needs	*Re-Envisioning Pharmaceutical Manufacturing: Increasing Agility for Global Patient Access*
Artificial intelligence (AI)	A machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments	*U.S. Code, Title 15, Chapter 119 – National AI Initiative (2020)*
Automation	The use of integrated advanced technologies and robotics to improve the efficiency and productivity of the biopharmaceutical manufacturing process	*Inside BioPharma 4.0: A Game-Changer in Manufacturing Innovation*
Biopharma 4.0	A comprehensive term that integrates diverse applications of data and digital technologies in biotherapeutic manufacturing, also known as Bioprocessing 4.0	*Inside BioPharma 4.0: A Game-Changer in Manufacturing Innovation*
Biopharma 5.0	A new ideology where technology and human intelligence are integrated to address not only productivity and profitability, but also environmental and societal challenges	*Biopharma 5.0: Restoring the Human Element*
Blockchain	A decentralized ledger system used for authenticating the information entered onto it, assuring product integrity from the point of origin to destination and real-time information in supply chain bottlenecks	*Blockchain, Biotech and Real-Time Auditing*
Cell line development (CLD)	The engineering of a cell line, often mammalian, to produce a therapeutic biomolecule or biologic	*What is Cell Line Development?*
Cloud-based data storage	A model where data is stored and analyzed remotely in cloud environments, as opposed to being downloaded and stored locally	*Cloud-based biomedical data storage and analysis for genomic research: Landscape analysis of data governance in emerging NIH-supported platforms*

Term/Abbreviation	Definition	Source
Computational chemistry	The use of computer simulations and modeling techniques to study and predict the behavior of molecules relevant to drug development	*Cloud-based biomedical data storage and analysis for genomic research: Landscape analysis of data governance in emerging NIH-supported platforms*
Continuous bioprocessing	The integration of multiple unit operations in biomanufacturing into a continuous, uninterrupted process flow	*A Methodology for Identifying Current and Future Skills Gaps: Future-Proofing the Bioprocessing Sector As It Embraces Industry 4.0 Principles, Part 1*
Critical material attribute (CMA)	A physical, chemical, biological, or microbiological property or characteristic of an input material that must be within an appropriate limit, range, or distribution to ensure the desired quality of the output material or final drug product	*Understanding Pharmaceutical Quality by Design*
Critical process parameter (CPP)	A key variable in a manufacturing process that must be controlled within specific limits to ensure the process consistently produces a product of the desired quality	*Understanding Pharmaceutical Quality by Design*
Critical quality attribute (CQA)	A physical, chemical, biological, or microbiological property or characteristic of a drug product, intermediate, or raw material that must be within an appropriate limit, range, or distribution to ensure the final product meets its intended safety, efficacy, and quality	*Understanding Pharmaceutical Quality by Design*
Cybersecurity	The protection of digital systems, data, and infrastructure used in drug development, manufacturing, and regulatory compliance from unauthorized access, cyberattacks, and data breaches	*U.S. Food and Drug Administration: Cybersecurity – Digital Health Center of Excellence*
Data analytics	Data generated throughout the biopharmaceutical production lifecycle that is processed and interpreted to allow for data-driven decisions	*Inside BioPharma 4.0: A Game-Changer in Manufacturing Innovation*
Data lakes	Centralized repositories that store structured and unstructured data at any scale	*Data lakes vs data warehouses in biopharma*
Data science	A core discipline in biopharmaceutical research combining data, computing power, and advanced analytics	*Ten simple rules to power drug discovery with data science*
Deep learning (DL)	A technique that involves finding a representation of data with multiple layers of abstraction using complex models that are composed of several layers of nonlinear computational units	*Current progress and open challenges for applying deep learning across the biosciences*
Digital fluency/literacy	Possessing a strong proficiency in data analysis, cloud computing, cybersecurity, and other newer emerging digital technologies	*A Methodology for Identifying Current and Future Skills Gaps: Future-Proofing the Bioprocessing Sector As It Embraces Industry 4.0 Principles, Part 1*
Digital Plant Maturity Model (DPMM)	A structured and accessible framework for evaluating plant-wide digital maturity and establishing target levels that align with an organization's overall digital strategy	*Digital Plant Maturity Model 3.0*
Digital twin	A virtual replica of a physical object, process, or system that uses real-time data to simulate its behavior	*Opportunities for Digital Twins in Bioprocess Development*

Term/Abbreviation	Definition	Source
Disruptive innovation	Introducing a product, service, or business model that significantly alters the way a sector operates, often challenging established market leaders and products	*Examining the Fundamental Impact of Disruptive Innovation in Healthcare*
Electronic lab notebook (ELN)	A software tool intended to replicate an interface much like a paper lab notebook that allows users to create, store, and share scientific records electronically	*Using an Electronic Lab Notebook*
European Medicines Agency (EMA)	A decentralized operating entity within the European Union (EU) with primary duties that include the scientific assessment, oversight, and safety monitoring of pharmaceuticals	*EMA official website*
Harmonized data strategy	A coordinated and standardized approach to managing data across the entire product lifecycle, ensuring consistency, integrity, and compliance across global operations	*An Integrated Approach to the Data Lifecycle in BioPharma*
Hybrid data + AI process model	An approach that balances knowledge-based traditional modeling and data-based modeling offered by AI/ML to create more accurate and efficient representations of complex processes	*Hybrid modeling for biopharmaceutical processes: advantages, opportunities, and implementation*
Industry 4.0	The next phase in the digitization of the manufacturing sector, driven by disruptive trends including the rise of data and connectivity, analytics, human-machine interaction, and improvements in robotics	*What are Industry 4.0, the Fourth Industrial Revolution, and 4IR?*
Industry 5.0	A new industrial revolution oriented to social and sustainability objectives	*Roadmap to Industry 5.0: Enabling technologies, challenges, and opportunities towards a holistic definition in management studies*
In silico process development	Computational models that investigate pharmacological hypotheses using methods such as databases, data analysis tools, data mining, homology models, machine learning, pharmacophores, quantitative structure-activity relationships, and network analysis	*What is in Silico?*
Integrated evidence generation planning (IEGP)	A strategic roadmap that aligns scientific, medical regulatory, health economics and outcomes research, market access and commercial objectives for pharmaceutical products	*Integrated Evidence Generation Planning (IEGP): How to Thrive in a Complex & Global Biopharma Environment*
Integrated evidence generation plan (IEP)	Accounting for the evidence needs of different functions and geographies across the life cycle of an asset, and then collaboratively determining how to meet them using a broad range of methods and data	*Integrated evidence generation: A paradigm shift in biopharma*
International Society for Pharmaceutical Engineering (ISPE)	A nonprofit organization dedicated to supporting its members by spearheading scientific, technical, and regulatory progress across the entire pharmaceutical lifecycle	*ISPE official website*
Internet of Things (IoT)	Refers to the integration of smart sensors, devices, and advanced analytics into biopharmaceutical processes	*IT/OT convergence and Industry 4.0's role in pharmaceutical manufacturing*
Laboratory Information Management Systems (LIMS)	Software to effectively automate workflows, integrate instruments, and manage samples and associated information	*Increase operational efficiency - What is LIMS?*
Machine learning (ML)	A set of techniques that can be used to train AI algorithms to improve performance at a task based on data	*U.S. Code, Title 15, Chapter 119 – National AI Initiative (2020)*

Term/Abbreviation	Definition	Source
Messenger ribonucleic acid (mRNA)	A single-stranded molecule transcribed from DNA that carries genetic instructions from the nucleus to the cytoplasm, where it guides the synthesis of proteins by translating codons into amino acids	*National Human Genome Research Institute*
Miniaturization	The process of reducing the size of a reaction mixture or assay	*What is miniaturization?*
Monoclonal antibodies (mAbs)	A category of therapeutic biological products that are specialized immunoglobulins produced from a single cell line, each with a specific target	*World Health Organization*
Multi-use systems	Conventional stainless-steel systems that undergo cleaning and sterilization between uses; commonly used in large-scale, high-throughput operations; valued for their durability and reusability, but require extensive infrastructure for cleaning, validation, and ongoing maintenance	*Large-Scale Capacity Strategies: Single Use, Multiuse, or Both?*
Next generation sequencing (NGS)	A massively parallel sequencing technology that offers ultra-high throughput, scalability, and speed	*Introduction to NGS*
Omics technology	Scientific approach associated with measuring biological molecules in a high-throughput way	*Evolution of Translational Omics: Lessons Learned and the Path Forward*
Operational technology (OT)	Hardware and software systems used to monitor and control physical processes. OT integrates with Information Technology (IT) systems to enable real-time data-driven decision making and smart automation.	*NIST - Computer Security Resource Center*
Pharma 4.0	The utilization of advanced technologies like Artificial Intelligence (AI), Internet of Things (IoT), and Big Data Analytics to enhance and optimize the manufacturing processes in the pharmaceutical industry	*Pharma 4.0: The Future of Pharmaceutical Manufacturing*
Predictive analytics	Data processed and interpreted throughout the biopharmaceutical production lifecycle that is used to anticipate issues before they arise for proactive quality management and process optimization	*Inside BioPharma 4.0: A Game-Changer in Manufacturing Innovation*
Process analytical technology (PAT)	A system used to design, monitor, and control biopharmaceutical manufacturing by measuring key quality and performance attributes of materials and processes in real time, to ensure consistent product quality	*Guidance for Industry PAT - A Framework for Innovative Pharmaceutical Development, manufacturing, and Quality Assurance*
Process intensification	An approach that strives for more efficient conversion of raw materials into products while minimizing resource usage in biopharmaceutical production	*Process intensification in the biopharma industry: Improving efficiency of protein manufacturing processes from development to production scale using synergistic approaches*
Quality by Design (QbD)	A structured, proactive approach to product development and manufacturing that emphasizes designing quality into processes from the beginning, rather than relying solely on testing after production	*NIST - Computer Security Resource Center*
Quality target product profile (QTPP)	A prospective summary of the desired quality characteristics of a drug product, identifying its Critical Quality Attributes (CQAs) to ensure safety, efficacy, and serve as the foundation for product development and design	*Understanding Pharmaceutical Quality by Design*

Term/Abbreviation	Definition	Source
Raman spectroscopy	An optical analysis technique that measures the chemical composition of samples using optical radiation interacting with molecular vibrations, resulting in the exciting radiation becoming inelastically scattered	*The role of Raman spectroscopy in biopharmaceuticals from development to manufacturing*
Real-time release testing (RTRT)	The ability to evaluate and ensure the quality of in-process and/or final drug product based on process data, which typically includes a validated combination of measured material attributes and process controls	*Opportunities and challenges of real-time release testing in biopharmaceutical manufacturing*
Robotics	A branch of technology that deals with the design, construction, operation, and application of robots which involves various advanced manufacturing techniques and often incorporates automation to enhance efficiency in production processes	*Opportunities for Modern Robotics in Biologics Manufacturing*
Single-use bioreactor (SUB)	Disposable systems usually composed of plastic materials, designed for one-time use; after use, they are typically discarded, eliminating the need for cleaning or sterilization	*Large-Scale Capacity Strategies: Single Use, Multiuse, or Both?*
Single-use system	A type of biopharmaceutical processing system designed for use during the production process of a single batch of therapeutics and then discarded	*Single-Use Systems: The Future of Biopharmaceutical Processing*
The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)	A global council that brings together regulatory authorities and the pharmaceutical industry from around the world to develop harmonised guidelines for the pharmaceutical sector	*ICH official website*
U.S. Food and Drug Administration (FDA)	A federal agency responsible for safeguarding public health by ensuring that food, cosmetics, and other consumer products are safe, effective, and accurately labeled	*Food and Drug Administration (FDA)*