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INDUSTRY 5.0 AND CIRCULAR ECONOMY IN BIOPHARMACEUTICAL MANUFACTURING: BRIDGING HUMAN-CENTRIC INNOVATION WITH SUSTAINABILITY

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ABSTRACT

Industry 5.0 extends and complements the technological developments of Industry 4.0 by introducing an evolution toward human-centred, flexible, and environmentally friendly industrial systems. This development is especially pertinent to the biopharmaceutical sector, which is under growing pressure to maintain excellent quality of the goods and regulatory compliance while cutting waste, increasing worker well-being, and optimizing resource efficiency. This review examines how robotics, circular supply chain models, human–AI collaboration, and sustainable facility design are transforming biopharmaceutical operations by synthesizing literature presented between 2015 and 2024. Four related domains are investigated using a thematic analysis approach:

(1) human-AI symbiosis in bioprocessing; (2) human-centric and zero-waste facility design; (3) robotics and automation in supply-chain circularity; and (4) integrated strategies for the circular economy across the value chain. Emerging industrial practices are exemplified by Pfizer, Moderna, Amgen, Biocon, and the Serum Institute, which of India. Key gaps in standard circularity metrics, empirical validation, and incorporated industry 5.0 structures in the biopharma industry are identified by the review. A theoretical framework is put forth to direct future investigations and managerial choices. The results show that Industry 5.0 can significantly accelerate environmental sustainability, enhance worker experience, and support resilient, future-ready biopharmaceutical manufacturing when added to circular economy principles.

Keywords: *Biopharmaceutical sector, regulatory compliance, human- AI collaboration, supply- chain circularity, Industry 5.0*

1. INTRODUCTION

One of the world's most resource-intensive and technologically advanced industries is the biopharmaceutical sector. Cell cultural backgrounds, fermentation, purification, safe handling, refrigeration, and complex distribution networks are all necessary bioprocesses. Significant amounts of chemical solvents, energy, single-use plastics, and cold-chain waste are produced by these processes. Sustainable and individualized manufacturing algorithms are essential as the world's requirement for vaccines, biological products, and customized medications keeps growing. Automation, robotics, sensors, and machine intelligence have already been introduced by Industry

4.0. Nonetheless, digitalization and operational efficiency continue to be its main priorities. By highlighting human-centred innovation, sustainability, and resilience, Industry 5.0 broadens this viewpoint. It positions people as cooperative partners with robotics and artificial intelligence rather than as machine supervisors. The Circular Economy (CE) framework advocates for reducing waste, reused materials, and eliminating resource loops throughout supply chains in tandem with this development. Biopharmaceutical manufacturing has a rare chance to switch from proportional to regenerative systems through combining CE with Industry 5.0. By combining human-centred design, robotics, circularity, along with sustainable innovation, this review explores the convergence of these two paradigms and assesses new research on their use in biopharma.

2. BACKGROUND STUDY

2.1 The advent of Industry 4.0 to the Industry5.0 transition:

Digital copies, automation, IoT-enabled devices, and predictive analytics were introduced by Industry 4.0. This is furthered by Industry 5.0, which places a higher priority on:

- Human-centric operations;
- Environmental responsibility and regenerative practices;
- Social accountability and well-being;

- Resilient supply chains. Industry 5.0 is a better match than fully automated models in biopharma, where human expertise is still necessary for aseptic procedures, quality control, and decision-making.

2.2 Principles of the Circular Economy in Biopharmaceuticals:

Reducing, reusing, remanufacturing, and recycling materials are the goals of the circular economy.

- Reducing or reprocessing single-use plastics;
- Recovering water and solvents;
- Reusing culture media byproducts;
- Redesigning packaging for reuse;
- Closed-loop applications logistics for bottles, syringes
- Returnable cold boxes are some of the CE strategies used in biopharma. The sustainability goals of Industry 5.0 are naturally aligned with CE.

2.3 Why Is Biopharma an Important Industry?

The biopharma industry has high ecological impact per unit output; stringent regulations; growing demand for sustainability reporting; extensive use of materials (filters, bags, tubing, connectors); energy-intensive cleanrooms and cold-chain systems. Therefore, the sector could undergo a revolution when Industry 5.0 innovations and the concepts of CE are combined.

3. METHODOLOGY

A narrative and thematic approach was adopted in this literature review.

3.1 Data Sources:

Peer-reviewed publications and case studies related to the subject were aquired from:Science Direct, Google Scholar, PubMed, ScienceDirect, Scopus, IEEE Xplore, and Industrial white papers (Pfizer, Amgen, EU Industry 5.0

3.2 Inclusion criteria:

- Published Works from 2015 – 2025
- Research studies applying to the topic of Industry 5.0, Industry 4.0, CE
- Case studies from pharmaceutical or biologicals production

3.3 Exclusion criteria:

- Non-pharma sustainability papers
- Studies not linked with human-focused or CE paradigms
- Opinion pieces without technical relevance

3.4 Thematic flow:

The literature reviewed is categorized into four primary themes:

- Human-AI collaboration
- Human-centric facility design
- Robotics & AI – Circular Economy – The Supply Chain
- Integrated CE in the biopharma industry

4. LITERATURE REVIEW

4.1 Bioprocessing Symbiosis:

Recent works have indicated that process analytical technologies assisted by AI, machine learning- based optimizations, and digital twins are redefining bioprocess development and manufacturing. The realities of biological variations, regulations, and contamination challenges make it impossible to automate bioprocessing. Industry 5.0 also supports "human-in-the-loop" approaches in which AI assists scientists instead of replacing them.

Collaboration between humans and AI has been achieved through the optimization of fermentation processes, predictive maintenance, the identification of deviations in quality, and adaptive control.

Other companies such as Pfizer and Amgen have used AI decision systems where the decisions are checked by human experts for verification.

Technically, when viewed in terms of circular economy, predictive analytics allows for early defect diagnosis, simultaneous maximal usage of raw materials, and minimization of solvent and water consumption.

4.2 Human-Centric and Zero-Waste Facility:
Industry 5.0 offers a new definition of biopharmaceutical facilities as human-centric sustainable ecosystems. The current literature focuses more on ergonomic cleanroom design, use of collaborative robots, smart environment, and digital worker guiding to minimize worker fatigue, contamination, and intensity.

At the same time, zero-waste technology solutions like solvent recovery systems, water recycle loops, recyclable bioprocess plastics, and modular cleanrooms are on the rise. Both Moderna and Biocon have adopted energy-efficient facility design and a material management plan.

Industry 5.0 enhances such strategies through the inclusion of labour well-being, responsible technology management, and sustainability metrics into building design and operation.

4.3 Robotics and Automation in Supply-Chain Circularity:
The biopharma supply chain creates a lot of waste due to cold chain packaging, logistics process inefficiencies, as well as expiration of products. There has been a rise in the use of collaborative robotics and AI-enabled traceability platforms for closed logistics loops, smart warehousing, as well as automated quality inspection.

RFID, blockchain, and IoT monitoring allow reverse logistics, packaging reuse, and contamination-free sorting. In addition, the Serum Institute of India and Pfizer have investigated returnable cold chain packaging concepts, automated inspection in vials, and robotic handling for sterile products.

Robotics therefore facilitates circularity by allowing for precision recovery, justified reuse routs, and secure material flows.

4.4 Integrated Circular Economy Strategies Across the Value Chain:
The strongest disruptive force may come from the integration of Industry 5.0 technologies throughout the biopharmaceutical life cycle. Emerging approaches involve Circular Product Design, Sustainable Procurement, Digital Material Passports, Life Cycle- Oriented R&D Strategies, or Product Return Management.However, the present-industry adaptation still lacks coordination. Industry 5.0 presents an overarching architecture for digital intelligence development in an intertwined human governance and circular innovation.

5. PROPOSED CONCEPT
A three-tier level framework includes the following:

Layer 1: Industry 5.0 Enablers
Collaboration between Humans and AI technology, Collaborative Robots/Cobots, Digital Twins, Ethical AI and workforce-centric digitalization.

Layer 2: Circular Economy Mechanisms
Resource optimization, Closed-loop manufacturing, Circular facility ecosystems, Lifecycle- driven design.

Layer 3: Sustainability Outcomes
Smaller environmental footprint, Improved labor well-being, Resistive environment, Long-term value-based approach.

Human agency plays a pivotal role in integrating technology with circular strategy. Human agency is the fundamental holistic force in a three-stage Industry 5.0–circular economy framework that links modern technological tools (Layer 1) with the circular economy mechanisms (Layer 2) to produce significant sustainability outcomes (Layer 3). Industry 5.0 reframes humans as engaged designers, supervisors, ethical guardians, and leaders within digitally enabled systems, in contrast to prior industrial paradigms that emphasised automation and efficiency as key drivers.

Instead of letting artificial intelligence (AI), cobots, and digital twins function only for cost or productivity optimisation, human agency is essential in coordinating these technologies with circular goals. Digital twins are used not only for performance simulators but also for waste stream prediction, material lifecycle optimisation, and environmental trade-off analysis through human judgement and domain expertise. Similar to this, collaborative robots enable flexible disassembling, remanufacturing, and repair operations—all crucial for closed-loop manufacturing but challenging to fully automate—by extending human physical capabilities and retaining human control.

Furthermore, workforce-centric digitalisation and ethical AI directly incorporate human values into technological systems. In areas like allocation of resources, predictive maintenance, or supply chain optimisation, human agency guarantees accountability, transparency, and fairness in algorithmic decision-making. By steering circular practices towards socially conscious and environmentally regenerative models, this ethical oversight keeps them from going purely extractive or exploitative.

Human actors, such as engineers, operators, environmental managers, and policy designers, are crucial in converting technological understanding into circular decisions at the circular economy level. In order to transform products for durability, flexibility for reuse, and recyclability, resource optimisation, lifecycle-focused design, and circular industrial ecosystems rely on individual innovation and architecture thinking. Humans provide long-term vision, cross-disciplinary integration, and contextual understanding, while technology provides intellectual ability and accuracy.

Finally, it is the role of human agency that facilitates this transition. Through purposeful actions, human agency ensures that it promotes reduced footprints, enhanced worker well-being, resilience, or value creation based on how industry enablers of Industry 5.0 are used. Thus, this phenomenon not only assists in sustaining this new industrial paradigm but also ensures that this new industry functions through its dynamic interface that promotes industry evolution from a technological advancement to a human-centred industry.

6. DISCUSSIONS

This review considers Industry 5.0 as a paradigm shift in both social and technological aspects that transcends automation. Unlike Industry 4.0, Industry 5.0 is built upon ethical governance, human creativity, and environmental stewardship.

Three key findings appear.

- To be specific, biopharmaceutical sustainability will demand regenerative design, and not just efficiency.
- Second, human-machine cooperation contributes to adaptive sustainability practices.
- Third, the best approach for the circular economy is aided by intelligence and human- management systems.

Nevertheless, empirical verification is limited, yet there are no standardized biopharma circularity performance metrics.

7. MANAGERIAL AND POLICY IMPLICATIONS

For industry leaders, it is important for them to understand:

- Employee-centric digital transformation
- Ethical AI governance
- Circular Design integration
- Sustainable facility investments

For Policymakers, it is important to understand:

• Circular manufacturing incentives

• Alignment of Industry 5.0 regulations

• Employee reskilling initiatives

• Standardized circularity scores

8. LIMITATIONS AND FUTURE RESEARCH:

The findings in this review are hampered by the narrative approach. Future topics of study should include:

• Empirical validation

• Longitudinal studies in industry

• Indicators for circularity for biopharma

• Human-centric impact measurement

• Maturity models of Industry 5.0

9. CONCLUSION

The integration of Industry 5.0 and circular economy thinking embodies a paradigm-shifting approach within the biopharma sector. In contrast to previous generations of industrial paradigms that emerged as a result of a focus on automations, speed, and cost competitiveness, Industry 5.0 provides a new impetus for the reorientation of manufacturing systems upon human-centricity, resilience, as well as a focus on the sustainable management of the environment. By being properly integrated with circular economy thinking, such a paradigm will allow biopharma companies to transcend linear “take-make-dispose” approaches to sustainable production.

In order to show that Industry 5.0 offers the socio-technical basis required to implement circular economy goals within highly controlled and biologically intricate manufacturing environments, this review synthesizes recent literature. The human-AI symbiosis preserves human authority in critical quality decision-making while enabling adaptive optimization of processes, early risk identification, and ongoing learning. Modular cleanrooms, intelligent safeguarding the environment, ergonomic systems, as well as closed-loop resource infrastructures are examples of how human-centric and zero-waste design of facilities can co-engineer sustainable development and operator well-being. Additionally, by facilitating contamination-free material handling, precise recovery, and identifiable reverse logistics across chilled-chain and packaging networks, cooperative robotics and automated systems support circular supply chains.

Crucially, this review shows that integrating Industry 5.0 as well as circular economy strategies throughout the biopharmaceutical value chain, as opposed to implementing them as discrete technological advancements or environmental initiatives, yields the most significant sustainability gains. According to the suggested conceptual framework, information technology, circular energy flows, and environmentally friendly performance outcomes are all connected by human agency. This human-centric structures perspective sets Industry 5.0 apart from earlier industrial models and offers a theoretical framework for future empirical research.

This review highlights a number of unresolved issues that need to be addressed in order to advance the field, despite growing interest from academia and industry. The majority of published work in biopharmaceutical contexts relies on philosophical discussions or pilot-scale reports of cases, and empirical evidence is still dispersed. Human-centric impact assessment tools, verified industry

5.0 maturity models, and standardized circularity metrics specific to biopharmaceutical processes are still lacking. Furthermore, cross-sector cooperation, workforce reskilling, as well as regulatory alignment are important enabling factors that call for thorough research.

In conclusion, Industry 5.0 presents a potent way to rethink biopharmaceutical manufacturing facilities as a resilient, regenerative, and socially conscious system when strategically combined with the concepts of the circular economy. The biopharmaceutical industry can reduce its environmental impact while simultaneously boosting innovation capacity, regulatory resilience, and public trust by integrating sustainability and human ideals into intelligent industrial architectures. In order to help researchers, practitioners, and policymakers move closer to a biopharmaceutical industry that is ready for the future and in line with the demands of global sustainability, this review offers an consolidated understanding and integrative framework.

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