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The Strategic Role of CDMOs in Europe's Biopharmaceuticals future

EFCG calls on policymakers to decisively imbed Contract Development and Manufacturing Organizations (CDMOs) within the Biotech Act's implementation roadmap. This is essential to secure Europe's leadership in biopharmaceutical innovation and to fortify the resilience of our supply chains.

CDMOs are the backbone of Europe's biopharmaceutical ecosystem, driving progress from early-stage development to large-scale production. Their expertise ensures supply chain flexibility, resilience, and innovation.
As the European Union prepares the Biotech Act, it is vital to recognise CDMOs as strategic partners, safeguarding competitiveness, sustainability, and autonomy in healthcare and biotechnology.

The Biotech Act aims to establish a coherent framework for biotechnology and biomanufacturing. While attention often centres on pharmaceutical companies and finished dosage form manufacturers, it is imperative to bring the pivotal role of CDMOs to the forefront. CDMOs are key contributors to Europe's biopharma resilience and innovation.

Distinctive features of Biopharmaceutical vs. traditional (small molecule) Pharmaceutical Supply Chains

- **Raw Materials**: Unlike traditional small-molecule APIs that rely on petrochemical intermediates and Asian-sourced complex intermediates, Biopharma also relies on agricultural feedstocks (e.g., sugars for fermentation and cell culture), unlike traditional small-molecule APIs. One challenge for biopharma is therefore securing sustainable biomass.
- **Processes**: Producing biologics requires the use of advanced bioreactors, strict adherence to Good Manufacturing Practices (GMP) standards and sophisticated engineering controls. These processes may include microbial process, mammalian cell culture, DNA/RNA based technologies , cell therapies or hybrid systems thereof such as bioconjugated modalities . Scaling up production requires significant investment and involves complex technological challenges.
- **Risk Profile**: Small molecule APIs are mainly threatened by geopolitical risks affecting their supply chains. The biopharmaceutical sector not only faces similar geopolitical risks but also must manage high investment requirements, the need for specialised expertise and complex regulatory requirements across most biological modalities.

Strategic Importance of CDMOs

- **Flexibility and Localisation**: CDMOs deliver localised manufacturing capacity, reducing dependence on global supply chains and supporting the EU's goals for securing its critical medicines.
- **Centres of supply and expertise:** A large portion of biopharmaceutical drug substance manufacturing is outsourced to Contract Development and Manufacturing Organizations (CDMOs). In advanced therapies—such as viral vectors, mRNA, or gene editing—over 70% of

production is handled by CDMOs. As a result, CDMOs play a leading role in driving manufacturing technology and innovation in the biopharmaceutical sector.

- **Innovation and Scale-Up**: CDMOs bridge the gap between R&D and commercial production, enabling rapid deployment of new therapies and technologies.
- **Economic Impact**: CDMOs drive investment in high-value infrastructure and create skilled jobs, strengthening Europe's industrial base.
- **Contribution to RU economic growth:** The output of CDMOs are projected to increase in the next decade, carried by growing therapeutic needs in the EU - including new therapies- and exports to other world regions. This trend will be further supported by a favourable Intellectual Property regime in Europe.

EFCG's unique contribution

EFCG (the European Fine Chemicals Group) plays a vital role in shaping discussions around the Biotech Act by:

- **Enhancing Supply Chain transparency** through mapping of biopharmaceutical value chains, which identifies sources of raw materials and key manufacturing hubs.
- **Providing sector-specific insights** by sharing practical examples of how fermentation-based production processes are used to produce essential and critical medicines and biologics.
- **Promoting policy alignment** by advocating for harmonised regulations tailored to the unique requirements of the biopharmaceutical sector, such as rules for Genetically Modified Organisms (GMO), Intellectual Property protection and funding for scaling up production.

EFCG's recommendations for the Biotech Act

- **Acknowledge CDMOs as strategic stakeholders** in securing, planning and funding programs that strengthen the EU's resilience in biopharmaceuticals.
- **Encourage investments in biomanufacturing Infrastructure** by providing targeted incentives to support the targeted development and modernisation of production facilities.
- **Ensure regulatory coherence** by harmonising standards for GMP, GMOs, sustainability and IP frameworks, making compliance simpler and more efficient.
- **Facilitate access to sustainable raw materials for biotechnology**, ensuring that the supply of feedstocks does not negatively impact food supply availability.

For more information please contact:
Maggie Saykali, EFCG Director
Alice Salmon, EFCG manager
efcg@cefic.be
https://efcg.cefic.org