

CEP 2.0: the pharmaceutical industry perspective

Karina Boszko

Head of Regulatory Affairs and Customer Technical Support Department,
Polpharma BU API

23.09.2025



CEP 2.0– main goals

Transparency

Enhance transparency for the health authority and MA Holders regarding the approvals that have been granted .

Minimise revisions

Minimise the number of revisions of the CEPs

Reducing Regulatory Burden

Aligning CEP requirements with global regulatory frameworks to facilitate acceptance by authorities outside Europe.



Expected Impact on Regulatory Submissions

Efficiency in Submissions

CEP 2.0 streamlines the regulatory submission process for faster and more efficient evaluation of API dossiers.

Reduced Review Timelines

The new system aims to shorten review timelines, speeding up regulatory approvals for manufacturers.

Improved Consistency and Predictability

CEP 2.0 enhances consistency and predictability in regulatory evaluations, benefiting both regulators and manufacturers.

Benefits Anticipated by Pharmaceutical Manufacturers

Clearer Regulatory Guidance

CEP 2.0 offers manufacturers clearer regulatory guidelines to better navigate product development and compliance requirements .

Faster Product Approvals

The updated CEP framework aims to expedite approval processes, reducing time to market for pharmaceutical products .

Improved Harmonization

CEP 2.0 promotes harmonization across regulatory bodies, facilitating smoother international market access.

Enhanced Quality Assurance

Enhanced quality assurance measures ensure higher product reliability and patient safety under CEP 2.0.



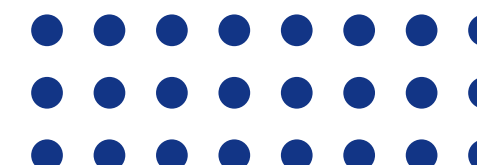
Positive Opinions and Benefits (1)

Improved Quality Assurance and Transparency

- CEP 2.0 enhanced focus on transparency and traceability
- The requirement to provide more detailed information about the manufacturing process, supply chain, and quality systems ensures better control over API quality and compliance .
- Companies see this as an opportunity to strengthen their reputation with regulatory authorities and customers by demonstrating robust quality systems .

Alignment with Global Regulatory Trends

- The new framework addresses modern regulatory concerns, such as elemental impurities risk assessments, data integrity .



Positive Opinions and Benefits (2)

Lifecycle Management and Continuous Improvement

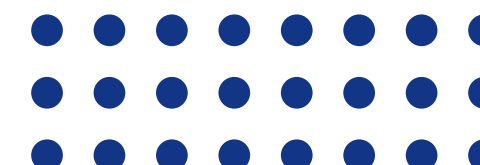
- The emphasis on lifecycle management of CEPs is seen as a proactive and forward-looking approach.

Increased Credibility and Global Acceptance

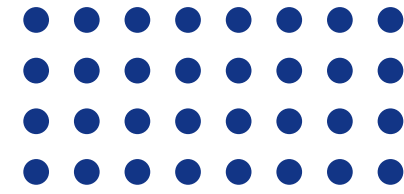
- Companies exporting APIs globally see CEP 2.0 as a way to enhance the credibility and acceptance of CEPs by regulatory authorities outside Europe.
- This can facilitate easier API registration on the markets where the CEP is recognized, such as Asian, Latin America, and Middle East.

Focus on Risk-Based Approaches

- The integration of risk-based principles into CEP management (e.g. nitrosamine risk assessments) aligns with modern pharmaceutical quality systems.



Opportunities



Competitive Advantage

Strengthens companies market position and increases their client base.

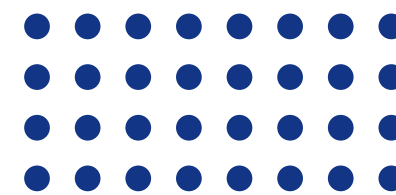
Improved Client Relationships

This builds trust and fosters long term partnerships with clients. -

Global Market Access

This opens up new revenue streams and expands the company's global footprint .





Concerns and Difficulties

Uncertainty and Supply Chain Challenges

The stricter requirements for supply chain transparency and traceability may lead to disruptions, particularly for companies relying on complex or multi-tiered supply chains.



Updating Existing Dossiers

Organizations must revise current dossiers to comply with new CEP 2.0 requirements, ensuring accuracy and completeness.

Financial and Operational Impact

Enhanced compliance measures raise operational costs, challenging sustainability for low-margin APIs.

Suggestions for Implementation

Clear Regulatory Guidance

Pharmaceutical companies seek detailed guidance and FAQs from EDQM for clear understanding of CEP 2.0 requirements .

Ongoing Industry -Regulator Dialogue

Regular consultations between EDQM and industry foster alignment, address concerns, and encourage collaboration .



Final Thoughts on CEP 2.0

Improved Detection

CEP 2.0 marks a significant step forward in regulating pharmaceutical active ingredients globally, enhancing quality control .

Collaboration for Success

Effective partnership between regulatory bodies and industry is crucial for a smooth CEP 2.0 transition and realizing its benefits.

Challenges and Opportunities

While CEP 2.0 adds complexity and costs, it offers growth opportunities for larger firms and emphasizes the need for industry support.

Supporting Global Public Health

Adopting CEP 2.0 principles helps ensure a safer, reliable API supply chain, supporting public health and regulatory integrity.

Vision for the Future



A Harmonized Global Regulatory Framework

CEP 2.0 positions EDQM and the pharmaceutical industry as leaders in global regulatory harmonization, ensuring consistent quality standards worldwide.



Enhanced Patient Safety

The implementation of CEP 2.0 will result in safer, higher-quality APIs, ultimately benefiting patients and improving public health.



A Stronger Industry -Regulator Partnership

Through collaboration, the pharmaceutical industry and EDQM can address challenges, drive innovation, and maintain the integrity of the pharmaceutical supply chain.



Thank You

For your attention!

