

EXPECTATIONS FOR IMPROVEMENTS TO JAPAN'S PHARMACEUTICAL REGULATORY FRAMEWORK IN RELATION TO API EXPORTS

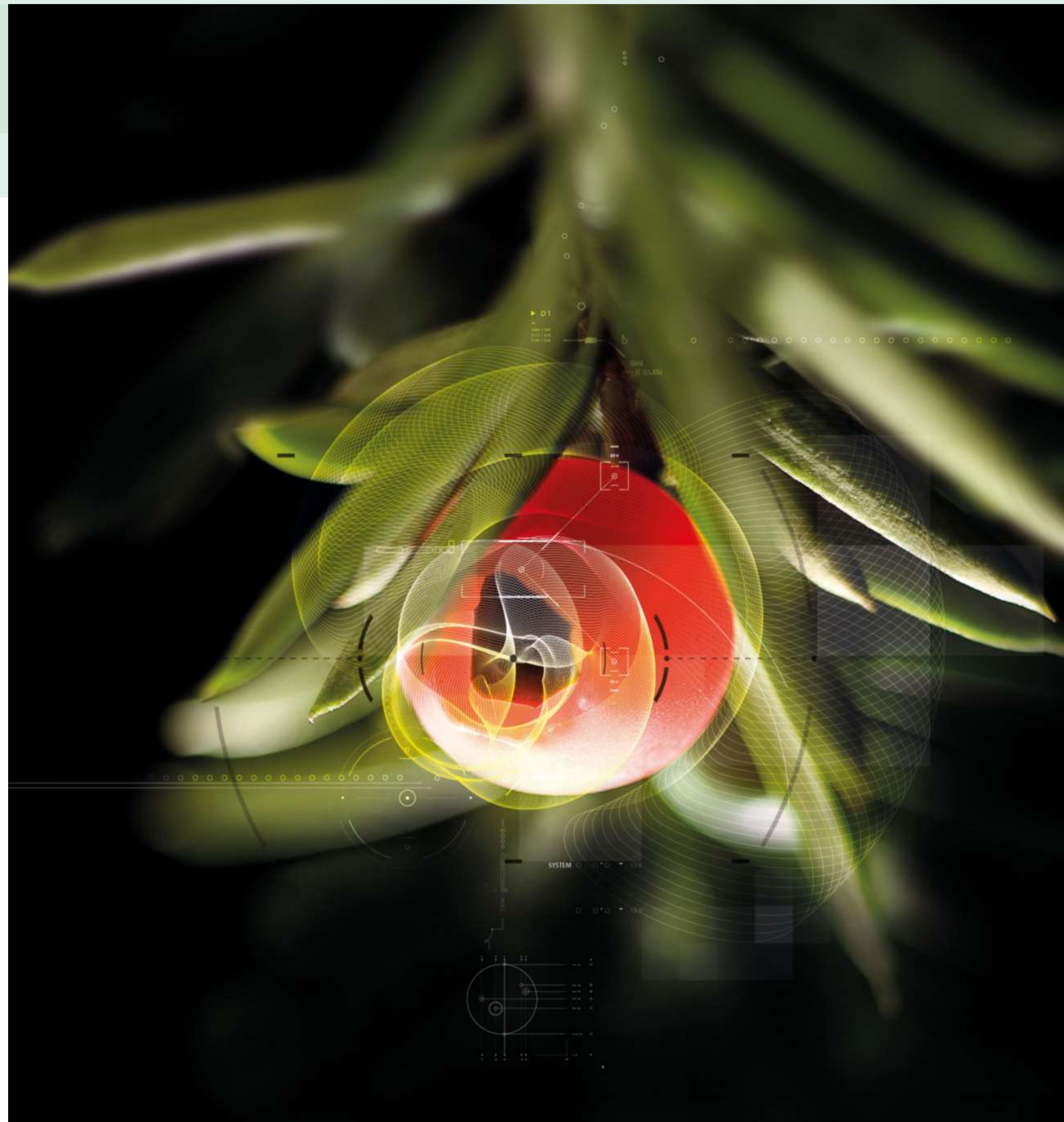
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Indena: a research-based Company since 1921

- Italian company founded in 1921, with an in-depth knowledge of **active ingredients derived from medicinal plants** for the pharmaceutical, food supplement, cosmetic and veterinary industries
- Expertise in high potency for the past 35 years, leveraging a long experience in taxanes, both in terms of process development and manufacturing as well as analytical development
- Global leader in the development of new **highly potent APIs (HPAPIs)** and **APIs** (obtained by plant extraction, synthesis, and precision fermentation) from early clinical stages to commercial manufacturing
- For over 40 years, Indena has been leveraging its solid pharmaceutical background for the nutraceutical field. Its **standardized extracts** have **full chemical characterization** backed by **quality, safety and efficacy tests**.



The Indena organization



HEADQUARTERS

Indena S.p.A.
Milano | Italy

RESEARCH CENTER

Indena S.p.A.
Settala (MI) | Italy

INTERNATIONAL BRANCHES

- **Indena Japan Co., Ltd. | Tokyo | Japan**
- *Indena Biotechnology (Shanghai) Co., Ltd. | China*
- *Indena Brasil Ltda | São Paulo | Brazil*
- *Indena S.A.S. | Paris | France*
- *Indena USA Inc. | Aliso Viejo | CA | USA*

FACTS AND FIGURES

- 4 production sites
- 900+ employees
- 100+ patent families
- 1000+ scientific studies
- 80+ countries served



API export to Japan: introduction

3

4/13

B3 %



- Japan is a key market for global API manufacturers.
- Exporting APIs to Japan involves unique regulatory requirements



Highlight opportunities to simplify processes

Alignment of Pharmacopoeias

Closer alignment between Ph. Eur. and JP:

Differences in analytical methods and specifications require Japan-specific testing or documentation

Extra workload for QA/QC and regulatory

Expected improvements:

Reduce test duplication.

Streamline batch release.

Improve global quality consistency.

Reduce additional regulatory dossier revision

DMF Preparation

3

4/13

83 %

Acceptance of CTD Module 3:

Current situation

- CTD Module 3 is widely accepted (EU, US, many other regions)
- Japan requires a dedicated DMF via caretaker and considers CTD Module 3 only as attached document of FD Application form ("J-MF").

Challenges

- Duplicate documentation.
- Higher costs and longer timelines.

Proposal

- Allow submission of CTD Module 3, with only minimal Japan-specific addenda when needed.



Management of DMF Amendments

Current situation

- Every change requires caretaker inquiry.
- No structured guideline for change classification.

Effects

- Delays, uncertainty, extra costs.

Proposed improvements

- Clear guidelines.
- Direct communication between the foreign DMF holder and PMDA for routine notifications.
- Predictable timelines.

Digitalization

Benefits

- Faster communication.
- Reduced admin steps.
- Better traceability

Digital tools for submissions

- Expand eCTD use.
- Create digital PMDA-company portal

Conclusion



Summary

- Align Ph. Eur. & JP.
- Accept CTD Module 3.
- Clear guidelines for changes.
- Increase digitalization.



Impact

- More efficient API exports.
- Lower costs and timelines.
- Stronger global collaboration.



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