



How can marketing authorisation holders best prepare for ePI – a view from the perspective of a global content service provider

Jessica Giardini, Member of Management,
mt-g medical translation GmbH & Co. KG

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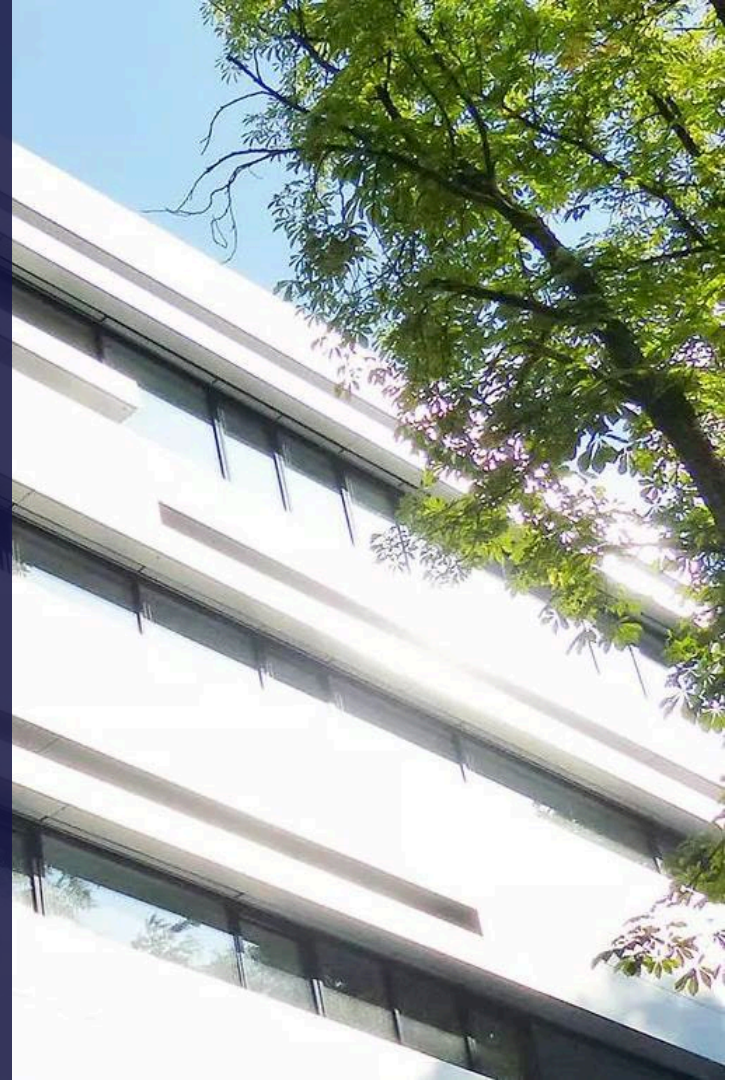
MEDICAL SPECIALISTS FROM THE START

mt-g is the leading global content service provider exclusively serving the medical and pharmaceutical industry in Europe.

- Founded in 1998
- Over 900 medical language specialists and experts worldwide
- Over 70 employees
- Privately-owned
- Headquarter: Germany

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Where are you in your ePI journey?

1. Haven't started
2. Planning / assessing
3. Pilot phase
4. Rolling out across products
5. Implementation phase

Why ePI?



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Regulatory Drivers and Opportunities

- ▶ Electronic Product Information (ePI): shift from static product documents (PDF, Word) to structured, machine-readable formats.
- ▶ The EU and other global regulators are driving this transformation to improve accessibility, transparency, and patient safety.
- ▶ Implementation of new EU pharmaceutical legislation



Benefits for Stakeholders

| Stakeholder | Benefit |
|------------------|---|
| Patients | Real-time, searchability, accessibility in patient's language |
| HCP | Integration with EHRs and decision support tools |
| Authorities | Easier compliance checks, reusable data |
| Pharma companies | Lower costs, more efficient workflows, increased consistency, higher safety |



What's changing with ePI?



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From Narrative to Structured Data

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    <text value="1. NAME OF THE MEDICINAL PRODUCT" />
  </code>
  <text>
    <status value="generated" /><div xmlns="http://www.w3.org/1999/xhtml"><p>FHIRion 100 mg powder for concentrate for s
  </div>
</section>
<section id="2ec797f3-b4ef-40a0-a373-d5446271b236">
  <title value="2. QUALITATIVE AND QUANTITATIVE COMPOSITION" />
  <code>
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    </coding>
    <text value="2. QUALITATIVE AND QUANTITATIVE COMPOSITION" />
  </code>
  <text>
    <status value="generated" /><div xmlns="http://www.w3.org/1999/xhtml"><p>One vial contains 100 mg of fhirionmab*. Af
```

▼ This medicinal product is subject to additional monitoring. This will allow you to report any new safety information. Healthcare professionals are asked to report any suspect adverse reactions. See section 4.8 for how to report adverse reactions.

1. → NAME OF THE MEDICINAL PRODUCT

FHIRion 100 mg powder for concentrate for a solution for injection

2. → QUALITATIVE AND QUANTITATIVE COMPOSITION

One vial contains 100 mg of fhirionmab*. After reconstitution each mL contains

From Narrative to Structured Data



Challenges for Marketing Authorisation Holders



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Data, Infrastructure & Process Challenges

- ▶ Legacy systems
- ▶ Fragmented, disconnected document-based content
- ▶ Non-centralized, partially manually translation processes throughout the company

Data, Infrastructure & Process Challenges

- ▶ Inconsistent language versions
- ▶ Regulatory requirements vs. technical requirements
≠ common language

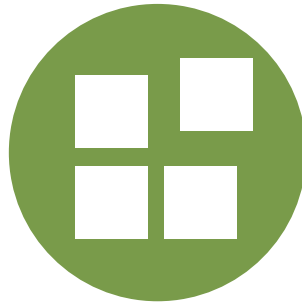


The Role of Language & Content Service Providers

Partnering for digital transformation



Regulatory
expertise



Content
modularization



Terminology



System
integration



What is your biggest challenge in preparing for ePI?

1. Legacy data fragmentation
2. Translation & terminology consistency
3. System integration
4. Regulatory change management

Best Practices Getting ready for ePI



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Recommendations: How to Start

- ▶ **Review:** existing systems, infrastructure, processes and product information content
- ▶ **Decide:** how to store and organize data in the future (corporation-wide? Silos?)
- ▶ **Evaluate:** systems and service providers



Recommendations: How to Start

- ▶ **Plan** and set priorities: data, regions, languages, timelines
- ▶ **Standardize** translation processes
- ▶ **Optimize** product information texts
- ▶ **Launch** pilot (transform text into FHIR)



Recommendations: Content Preparation

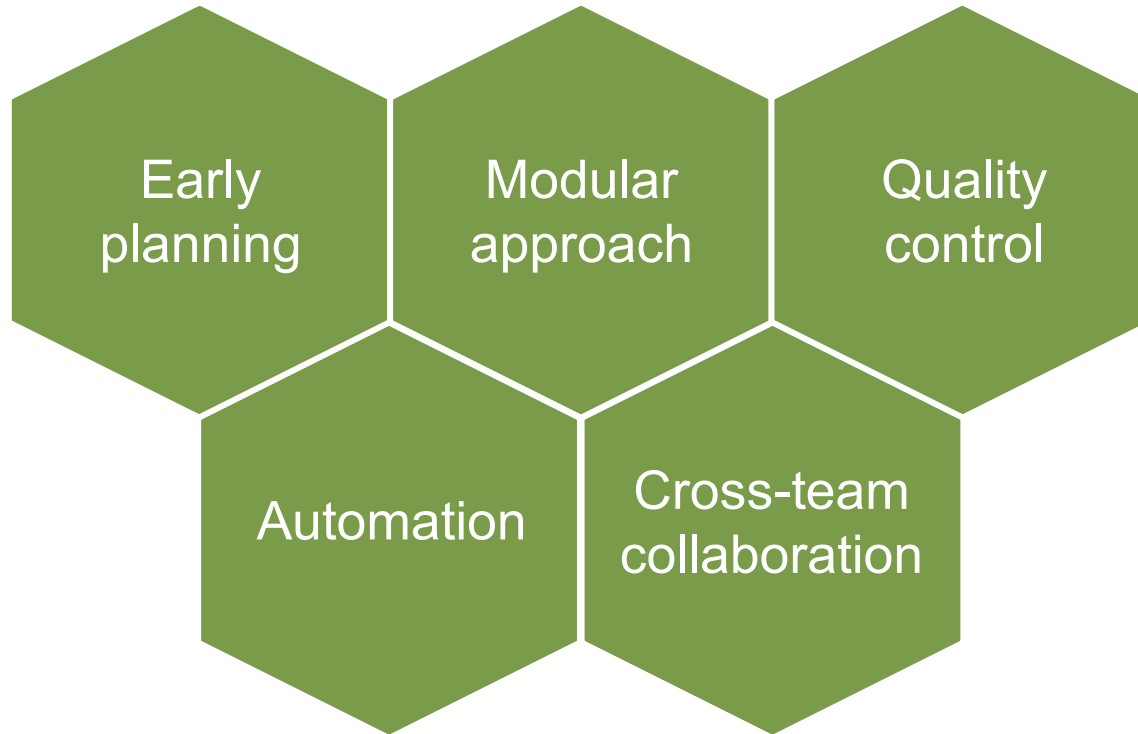
Review existing product information texts for:

- ▶ Consistency with the (English) master text
- ▶ Consistency across all strengths and dosage forms
- ▶ Consistency across product groups

Recommendations: Content Preparation

- ▶ Implement corporate terminology
- ▶ Harmonize SmPC & PIL (if applicable).
- ▶ Create database in all languages ("translation memory" and "term base"), if not already available.

Recommendations: Key Success Factors



Recommendations: Key Success Factors

- ▶ **Train staff**
- ▶ **Make sure that Regulatory and IT speak a common language**



Advantages of Professional ePI Approach



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Recommendations: Key Success Factors

A professional ePI strategy ensures:

- ▶ higher text quality
- ▶ scalability for new products
- ▶ future-proof documentation structures
- ▶ efficient workflow management and integration

The Role of Language & Content Service Providers

Integration Example



Conclusion



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Conclusion

Start your ePI pilot today — partner with experts who understand the regulatory, linguistic and technical dimensions.





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Thank you!

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Contact



Jessica Giardini
Member of Management
Head of Project Management
Pharma

Tel. + 49 731 176397 - 41
jessicagiardini@mt-g.com

www.linkedin.com/in/jessica-giardini2

mt-g medical translation
GmbH & Co. KG
Stuttgarter Straße 155
D-89075 Ulm

Tel: +49 731 176397 0

info@mt-g.com
www.mt-g.com



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