Healthcare Supply Chain
Importance of collaboration based on global standards

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Agenda

- Why do we need global standards?
- Where do we need global standards?
- Who benefits from global standards?
- Best practices
- Country-specific requirements
- Conclusions
Why do we need global standards?

- Healthcare is a **global business** where supply chain partners **exchange** goods and information

- Manufacturers often apply ‘center of excellence’ concepts

- World-wide / cross border deliveries

- Country-specific Auto-ID regulations have major impact on product assortment and on supply chain management
  - Smaller production lots, additional costs for warehousing, additional administration efforts, etc.

- ‘Late-fit concepts’ often not possible
  - 3-level packaging hierarchy, product protection, no access to inner packaging levels outside the production environment, etc.
Why do we need global standards?

Global standards are key success factors for process improvements.
Where do we need global standards?

1. **Machine-readable identification**
   - Encoded data
   - Bar code carriers
   - Application standards

2. **Electronic data exchange**
   - Data pools + formats
   - Identification keys
   - Data attributes

3. **Traceability**
   - Clear responsibilities
   - Process transparency
   - Realistic level of granularity (i.e. lot no based or serialization)
Who benefits from global standards?

The whole healthcare community!

- Manufacturers
  - Investment security
  - Lean processes
- Purchase organizations
  - Access to harmonized/qualified data
- Healthcare providers
  - Critical mass for i.e. bar code usage easier to achieve
- Patients
  - Enhanced patient safety (i.e. right patient – right product)
- Regulators
  - Enables effective traceability, market surveillance / vigilance, other

But any deviation complicates the supply chain …
Best practice 1: **UDI Initiative**

- Supply chain stakeholders are involved in the development of a global harmonized approach for UDI through the GHTF
- Risk-based approach
- Avoid over-interpretation

**Our recommendations:**
- Do not ignore economical impact of regulations, both on the side of the manufacturer and on the side of the provider
- Low-hanging fruits first
Best practice 1: **UDI initiative**

- Technical and financial impact of implementing bar codes and UDI varies per packaging level
- Utilization by providers too…

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**Bar codes in healthcare**

- Do we need bar codes for everything?
- Nobody intends to scan everything at consumption unit level

<table>
<thead>
<tr>
<th>Logistics unit</th>
<th>Sales unit</th>
<th>Consumption unit</th>
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<tbody>
<tr>
<td>Impact on manufacturers</td>
<td>Utilization by providers</td>
<td>Gap</td>
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Best practice 2: **GDSN**

- GDSN will help all supply chain stakeholders to **minimize efforts** regarding data administration and country-per-country data upload procedures.

- Usage of GLN and GTIN as the single key for partner and product identification will **avoid misunderstandings**.
Best practice 2: **GDSN (cont’d)**

- **Functionality of GDSN is proven**
  - Global pilot (Australia – US / 2008) successfully completed
  - Demonstrated how the GDSN supports healthcare supply chain and product data needs
  - Demonstrated how the GDSN works across international boundaries
Best practice 3: **Global Traceability Standard**

Published in March 09, the Global Traceability Standard for Healthcare (GTSH) is the first time ever to have a **process description** for tracking & tracing healthcare products

- includes physical flow and information flow
- contains definition of minimum requirements
- to comply with regulatory guidance on recalls
- to reduce business risks above and beyond legal compliance
- to support effective logistics and quality management
- etc.
Best practice 3: Global Traceability Standard (cont’d)

Published in April 09, the GTSH Implementation Guide assists any and all stakeholders to implement a traceability system in line with the GTSH

- Common language
- How and what to track & trace
- Which data to exchange
- Which technologies to use
- Etc.
Country-specific requirements

- **Avoid** country-specific requirements / regulations

- **Existing country-specific regulations** should be
  - identified
  - analyzed
  - discussed
  - **migrated** to global standards
  - within a suitable time-frame

- **Pre-requisite**
  - **proven** global standards that meet country-specific needs must be available
Conclusion 1: Believe

Eucomed and B. Braun

- Believe in global standards
- Have been contributing to its development since the beginning
- Endorse GS1 Standards and recommend its step-by-step implementation

BUT the best standards won’t be beneficial if not used across the entire supply chain - ‘gear box effect’

- Manufacturers deliver the pre-requisites
- Healthcare providers have to be ready to use those global standards
  Planning resources, investments, process adjustments, etc.
Conclusion 2: Move forward

Let’s not stop half way
Conclusion 3: Keep it simple

The most important key success factors are:

- Ability of all supply chain stakeholders and regulators to **contribute** to the standards development process

- Willingness to **adopt** the global standards or to promote its usage

- Keep the **balance** between theoretical models, technical feasibility and cost effectiveness of any solution

“**It’s better to start at a lower level in an appropriate timeline than to wait for the perfect solution for ever !**”

“**Simple solutions break down barriers !**”
Thank you very much for your attention!

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