Regulatory Affairs

Berlin, Germany
Jackie Rae Elkin

The global language of business
www.gs1.org
Objectives

• Organize the industry around a single position to drive future standards and influence regulations around auto identification of healthcare products

• Work with existing healthcare industry organizations and healthcare advocacy groups in delivering the position of HUG
  - Healthcare Ministries, Regulatory Agencies
  - AdvaMed, Eucomed, and other trade associations
Scope

- Auto-Identification in Healthcare
- Medical Devices and Pharmaceuticals
- International, National, Regional Laws, Regulations, Standards
• Maintain global reference of applicable laws, regulations, standards

• Provide guidance to HUG membership including governmental agencies and healthcare trade associations

• Specific responses to authorities regarding public policy
# Regulatory Baseline

<table>
<thead>
<tr>
<th>Country</th>
<th>Region</th>
<th>Issue</th>
<th>Description</th>
<th>Resolution</th>
<th>Source</th>
<th>Date</th>
<th>Document</th>
<th>Page</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>Asia</td>
<td>Medical Device</td>
<td>Product recall due to manufacturing defect</td>
<td>Conduct recall and issue new products</td>
<td>GS1</td>
<td>2007-01-01</td>
<td>GS1 - Medical Device Recall Guidelines</td>
<td>2</td>
<td>GS1 - Medical Device Recall Guidelines</td>
</tr>
<tr>
<td>Europe</td>
<td>Europe</td>
<td>Pharmaceutical</td>
<td>Lack of adequate documentation</td>
<td>Implement quality control processes</td>
<td>EMA</td>
<td>2007-02-01</td>
<td>EMA - Quality Control Guidelines</td>
<td>3</td>
<td>EMA - Quality Control Guidelines</td>
</tr>
<tr>
<td>Germany</td>
<td>Europe</td>
<td>Medical Device</td>
<td>Adverse event reported</td>
<td>Conduct investigation and report findings</td>
<td>BfArM</td>
<td>2007-03-01</td>
<td>BfArM - Medical Device Regulation Guidelines</td>
<td>5</td>
<td>BfArM - Medical Device Regulation Guidelines</td>
</tr>
</tbody>
</table>

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Actively engaged in communication and dialogue with Healthcare Ministries, Regulatory and Governmental Agencies

Examples:
* Ministry Health Labor Welfare – Japan
* Spain Ministerio de Sanidad y Consumo, Madrid
Italian Healthcare Ministry
* UK Department of Health
Australia National Blood Authority
New Zealand Ministry of Health

Public Health Agency Canada

* United States - Food and Drug Administration
China - State Food and Drug Administration
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