



# Regulatory Affairs

Berlin, Germany  
Jackie Rae Elkin

The global language of business

[www.gs1.org](http://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



## Deliverables

- 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





## Working Communication

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



## Contact details

Jackie Rae Elkin

**Regulatory Quality Compliance Manager**

T 763) 514-5306

E [jackie.elkin@medtronic.com](mailto:jackie.elkin@medtronic.com)

The global language of business

[www.gs1.org](http://www.gs1.org)