

# Plenary Session 9th GHTF Conference

Total Product Lifecycle:

A focus on Postmarket Surveillance &  
Vigilance

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# The Total Product Lifecycle

Concept

Prototype

Pre-clinical

Clinical

Manufacturing

Marketing

Clinical Use

Obsolescence

Pre-clinical/Clinical

Conformity assessment

Vigilance

Postmarket Surveillance

# Vigilance

## – Reactive

- Adverse Event Reports
- Investigation & Information Exchange
- Regulatory Intervention (Enforcement)
- NCA Reporting

# Surveillance

## – Pro-active

- Compliance Testing
- Quality System Audits
- Technical File Audits
- Postmarket Clinical Follow-up

# GHTF Strategic Directions

- Goal 3
  - The GHTF will seek to evolve beyond convergence of regulatory requirements to embrace mutual acceptance of common data submissions, pre-market conformity assessment processes, quality systems, quality systems auditing, and broad sharing of post marketing experience

- Goal 3 - Tasks
  - GHTF members, having met eligibility criteria, will participate in the National Competent Authority report (NCAR) vigilance system

# Speakers

- **Dr David Feigal Jr** - Director CDRH, FDA
- **Dr David Jefferies** - CEO, MDA
- **Mr Roland Gerard** - Director, Regulatory & Clinical Affairs, St Jude Medical, Europe
- To be followed by 30 minutes discussion with speakers

# This session will focus the post market surveillance and vigilance parts of the product lifecycle -

- After design, clinical trial and regulatory approval, what then.
- What are the demands on manufacturers and their representatives.
- What assumptions do surveillance and vigilance systems make about manufacturer's technical files and quality systems.
- What lessons from pharmaceutical and other industries.

