Technology for Life

# Healthcare IT zwischen Regulierung und Innovation

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Dräger products

protect, lives

support and

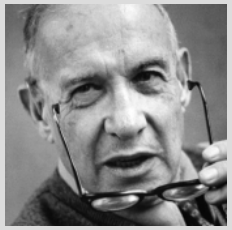
save .

# Guiding philosophy
What we stand for

Technology
for Life

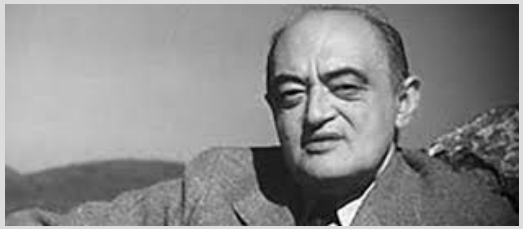
# Innovation
## Definition of the term for today

- Something completely New or a significant Change of the existing
- Creates a Value add, which:
  - is felt and/or quantifiable for the customer
  - can be measured in hard numbers for the company



*"Innovation is the specific instrument of entrepreneurship… the act that endows resources with a new capacity to create wealth." – Peter Drucker*

*„Implementation of a technical or organizational new concept not just because of it's invention" – Joseph Schumpeter*



# Regulation

OECD Definition:

Regulation is broadly defined as imposition of rules by government, backed by the use of penalties that are intended specifically to **modify the economic behavior of individuals and firms in the private sector**. Various regulatory instruments or targets exist. Prices, output, rate of return (in the form of profits, margins or commissions), disclosure of information, standards and ownership ceilings are among those frequently used.

# Regulation

**Preamble MDD 93/42/EEC:**

Whereas the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonized in order to guarantee the free movement of such devices within the internal market.

**FDA Investigations Operations Manual:**

Vision
All food is safe; all medical products are safe and effective; and the public health is advanced and protected.

Mission
Protecting consumers and enhancing public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products.

# Regulation of Innovation
# Rough overview

| | Europa | USA |
|---|---|---|
| **Classification** | Rule based | Catalogue based |
| **New technology** | Based on scope of Notified Body. Same rules apply. | Intensive involvement of FDA (De Novo Classification Process, PMA, IDE, HDE) |
| **Requirements** | Abstract, Essential Requirements | Guidance based |
| **Standards** | Harmonized Standards, used to fulfill ER | Recognized Standards acc. product code |

# FDA Innovation Programs

**CDRH Innovation Initiative February 2011:**

Facilitate development and regulatory evaluation of innovative medical devices

Prepare for and respond to transformative innovative technologies and scientific breakthroughs.

## Innovation Pathway

INNOVATION PATHWAY at FDA

Patients deserve faster access to safe and effective medical devices that address unmet public health needs. The FDA's Innovation Pathway is a new way of doing business within our existing regulatory framework that could yield significant benefits to patients in the U.S. by giving them first-in-the-world access to medical devices, including those with breakthrough technology.

The Innovation Pathway is an evolving system designed to help safe, breakthrough medical products reach patients in a timely manner. The Pathway ultimately aims to shorten the overall time and cost it takes for the development, assessment and review of medical devices, and to improve how FDA staff and innovators work together.

*Innovation Pathway at FDA*

By engaging with innovators much earlier, more collaboratively, and in new ways, we believe we can reduce the time and cost of the entire process of bringing safe and effective technologies to patients more quickly.

On April 9, 2012, the FDA's Center for Devices and Radiological Health (CDRH) launched its second version of the Innovation Pathway, called "Innovation Pathway 2.0."

Innovation Pathway 2.0 offers new and modified tools and methods to deepen collaboration between the FDA and innovators early in the process, prior to pre-market submission, with the goal of making the regulatory process more efficient and timely.

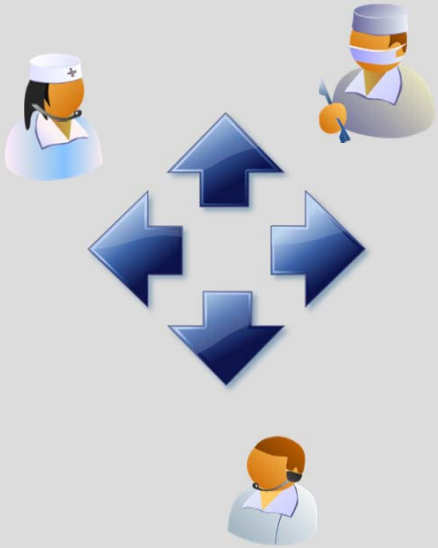
The Pathway also serves as a living laboratory to test new tools and methods for breakthrough devices that we may also apply to other technologies to enhance all of our device pre-market programs.

Technology
for Life
Innovation
that sets standards

# Base for innovation
# Standards - consensus

Customers

Patients



Industry

Authorities

Test Houses

Consultants

# Challenges for Interoperability Standards

**Authorities:**

US:
- active involvement in standardization process
- struggle with device – system – network regulation concepts
- nationally driven

EU:
- only passive involvement by harmonization process and EU consultants
- Include systems and combinations (since 1993) and operators (Betreiber) in regulation
- European approach by changing responsibilities

**National Standards committees:**

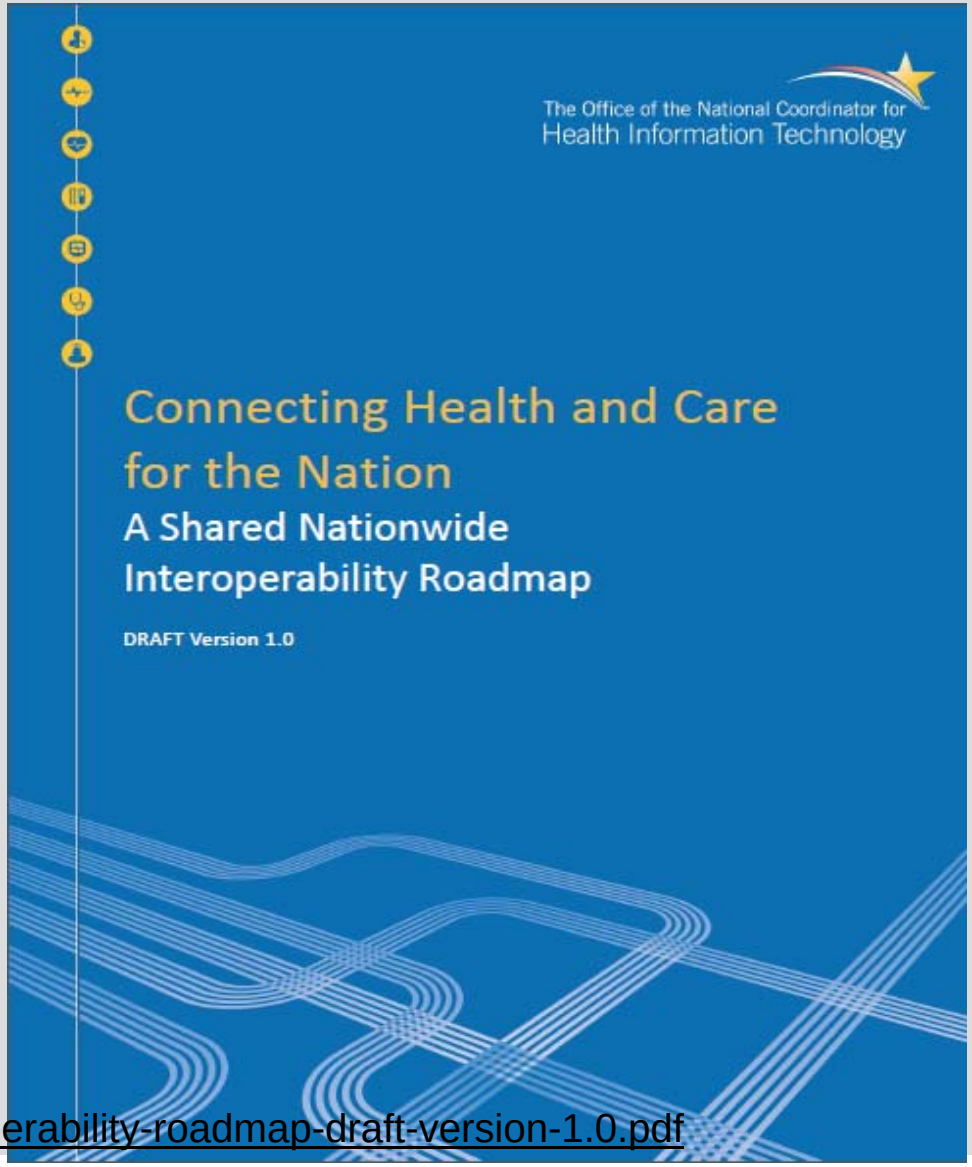
US:
- Top Down approach
- nationally driven

Germany:
- Bottom up development
- internationally driven

# Interoperability Standards
# Initiatives US

Achieving a better care system and better health for all through health IT interoperability,
requires work in 3 critical pathways:

1) Implementing standards
2) Motivating the use of those standards through appropriate incentives
3) Creating a trusted environment for the collecting, sharing, and using of electronic health information




http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf

# Interoperability Standards Initiatives Germany

Standardized Interoperability in open environment. Organizations can design systems for their clinical processes independently from proprietary manufacturers:

1) As part of the risk management, manufacturers and operators must be able to make risk analysis of individual components in the flexible integration via open interfaces developing an overall risk assessment.

2) Support the necessary security and achieve interoperability, registration and operation of plug and play architectures in ORs and other medical technology-intensive areas, including complex IT infrastructures.

# Interoperability Standards
# Contribution from Industry

**Cornerstones in standardization:**

- Definition of clinical scenarios for process specifications per level
- Open, service-oriented health delivery platform with a common architecture and pre-implemented standards and profiles
- Software tools for verifying syntactic interoperability
- Software tools for validating semantic interoperability
- Validation of usability
- Verification of security measures
- Validation of safety measures

**Questions:**

- Who needs to participate to fill new roles and structure?
- Who is driver and stakeholder for international standards?

Dräger

# Thank you
# for your attention.

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