Medical Devices: Innovation and the Regulatory environment

AHWP – Hong Kong, November 5, 2009

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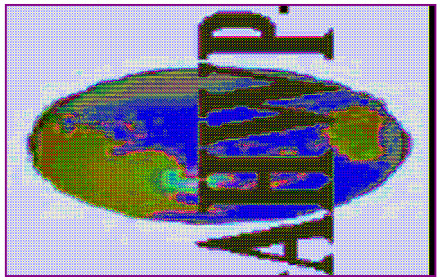

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Discussion content

- Why innovation ?
- Regulatory difficulties - example
- Role of AHWP - GHTF in building harmonized regulations

Why do we need innovation ?

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Managing health in the 21st century: A shifting approach

From…	… To
Personal ignorance of health	Personal management of health
Cure	Prevention
Late diagnosis	Earlier diagnosis
Acute / life threatening condition	Milder / chronic condition
Gross intervention	Minimal intervention
Long rehabilitation	Shorter rehabilitation
High total cost of episode	Lower total cost of episode
High societal cost	Containment of societal cost
High personal impact	Lower personal impact

Trends in technology

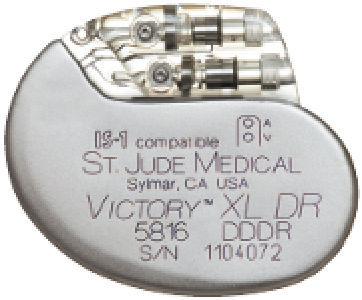
- Miniaturization of devices
- Replacement organs
- Molecular and genes based diagnostics
- Nano technologies
- Drug / devices / biologics combination
- Telemedecines
- Health Information technologies

Pacemaker evolution

2008

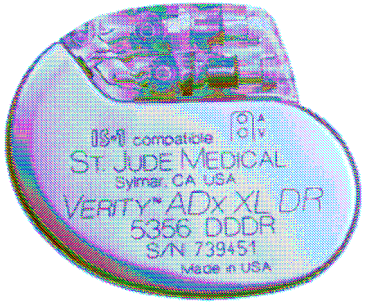
Automatic AV Optimisation

2006



Ventricular Intrintsic Preference

2003



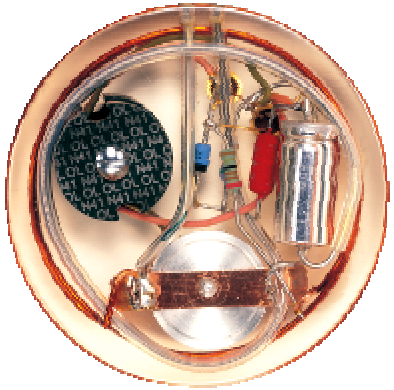
AF prevention

1986

Sensor Controlled

Intelligence implementation

1958



1988

1992

1994

Technology miniaturization

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Syringes


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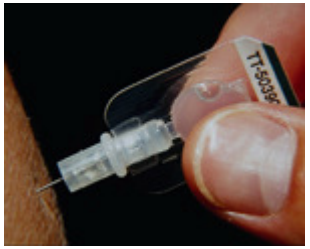
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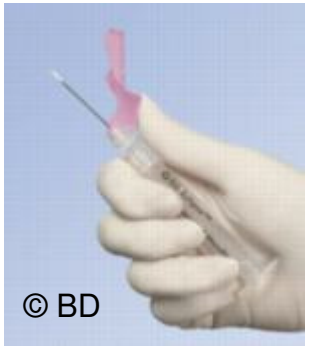
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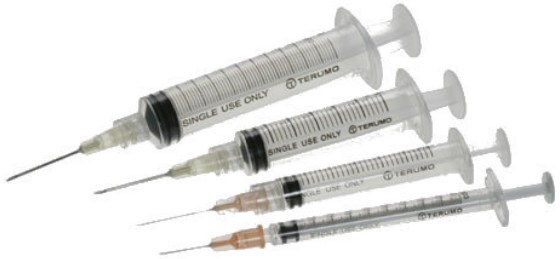
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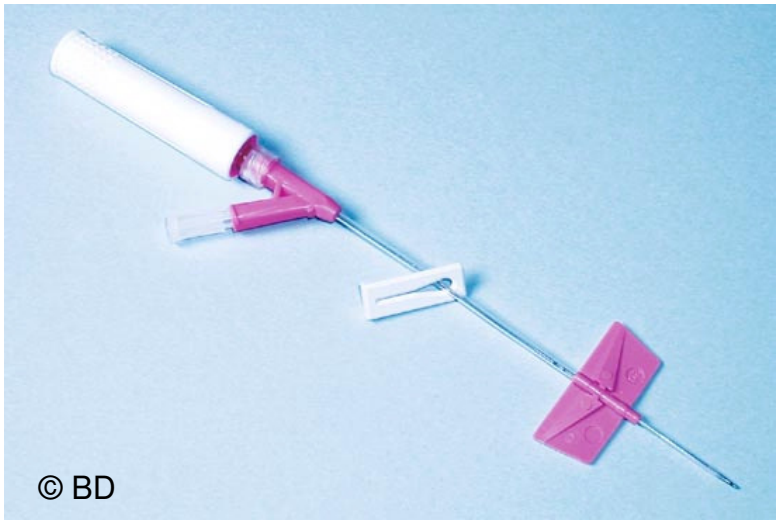
Catheters



Health = Wealth

- Pace of technological advancement
- Ageing population
- Health = Wealth

  “Innovation in our health sectors is of tremendous importance to the competitiveness of our economies and the well being of our citizen”

  G. Verheugen, Vice president of the European Commission

Example - Drug device combination - from Metallic coronary stents to Drug Eluting Stents

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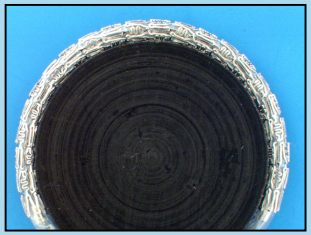
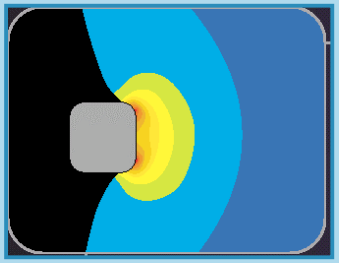
Contributors to Metallic Stent Performance

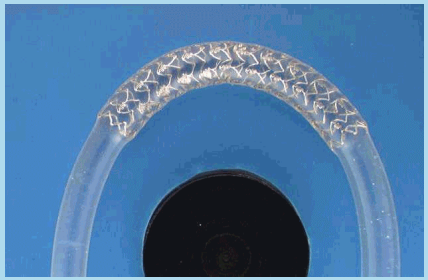
Ease-of-Use:
- Deliverability
- Visibility
- Flexibility



Minimal Injury:
- Strut Thickness
- Metal Volume



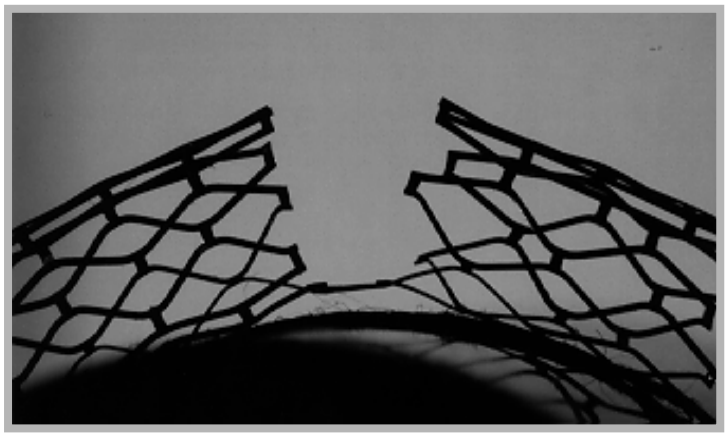
Conformability:
- Scaffolding on a bend

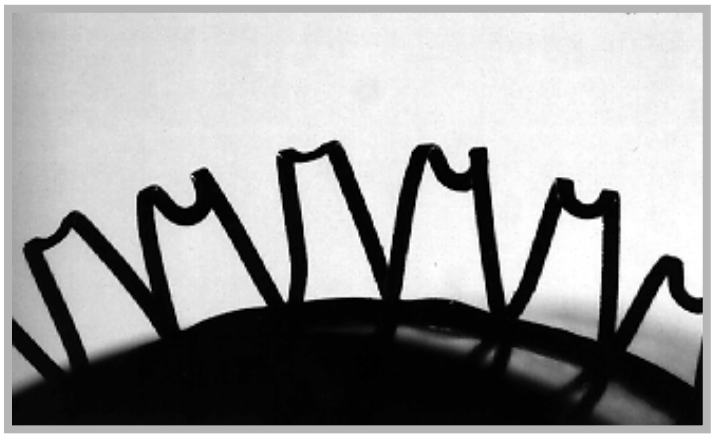


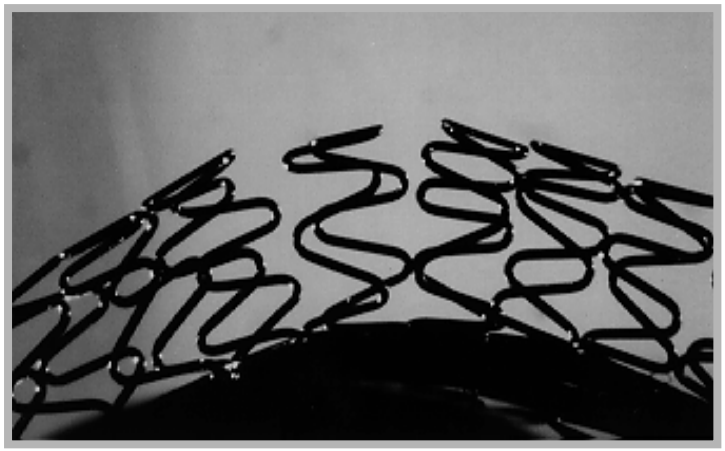
Clinically Proven Design

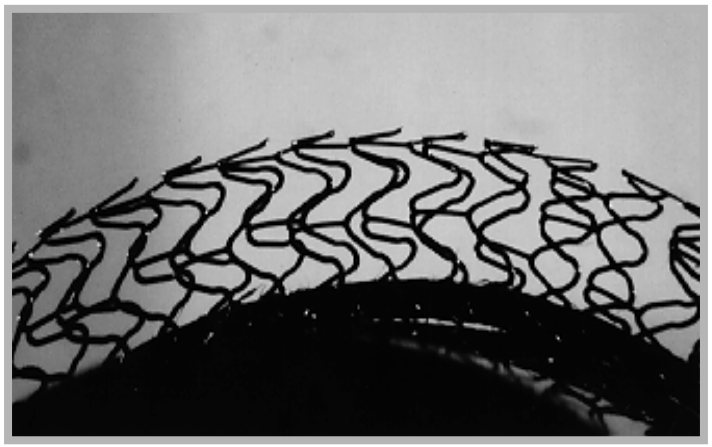
Clinical Data Outcomes
- Acute
- Long Term

Early Metallic Stents



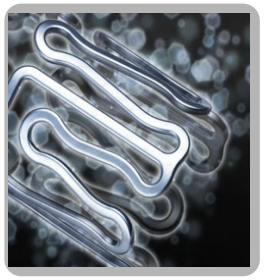




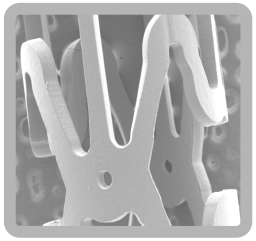


Future Innovations…

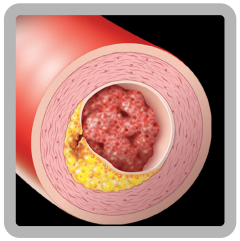
DES



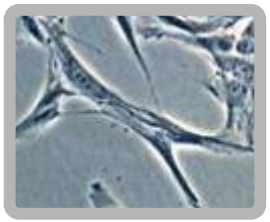
Bioabsorbable Stents



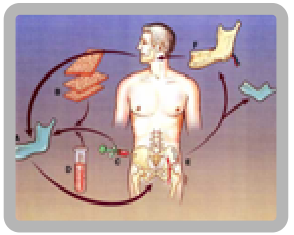
Vulnerable Plaque



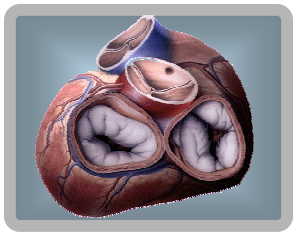
Cell Therapy



Site Specific Therapy



Structural Heart Disease



TODAY TOMORROW FUTURE

Currently in development. Not available for sale.

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Regulatory Challenges

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Regulatory Challenges - Multiplicity of reviews

- Europe:
  - EU
    - CE Design Dossiers under 93/42/EC - Consultation with drug Authorities Use of accredited Notified Bodies
    - Local RA submits to CA for clinical trial submissions; CA liaison
  - Non-EU
    - Country-specific documents (Certificates or other legalized documents)
- Asia / Pacific:
  - Country-specific dossiers (country-specific documentation / translations) based on CSDT
- Latin America
  - Submission country-specific documentation. Little recognition of STED

Regulatory Challenges – Multiplicity of reviews

- Canada:

  Market-approval submissions & Clinical Trial Applications

- Australia:

  Market-approval submissions. Loosely based on EU system

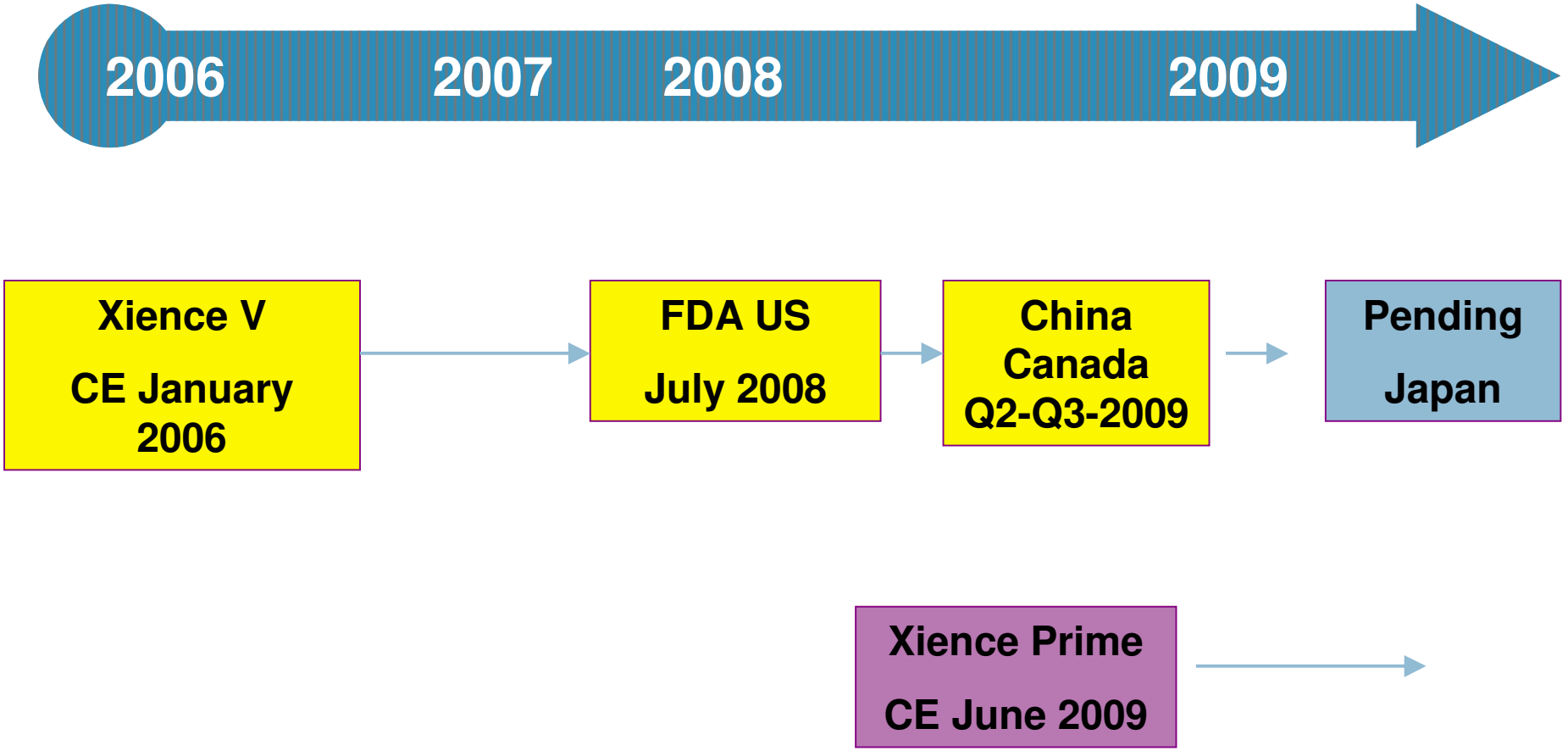
- Japan:

  CTN, Shonin, Partial Change Submissions, very specific request from PMDA

  Quality related documents such as Foreign Manufacturer Accreditation, 3rd Party

  Lack of harmonization with standards (e.g ETO residual levels)

DES - Xience family



Role of harmonization bodies GHTF / AHWP

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Assess together the challenges going forward

- Identification of new risks
  - Technologies
  - Materials
- Identification of novelties - Novelty tool
- Information and training of users
- Humanitarian availability
- Lack of available standard. Pace of development
- Suitability of existing regulatory regimes
  - Pre market
  - Post market and identification of early signals

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

GHTF

Benefits include:

- Potential cost and time savings for regulators and manufacturers when device when expanding to international markets
- A higher level of safety assurance for consumers, regardless of where products are manufactured
- Broader and quicker patients access to innovative technologies developed around the world

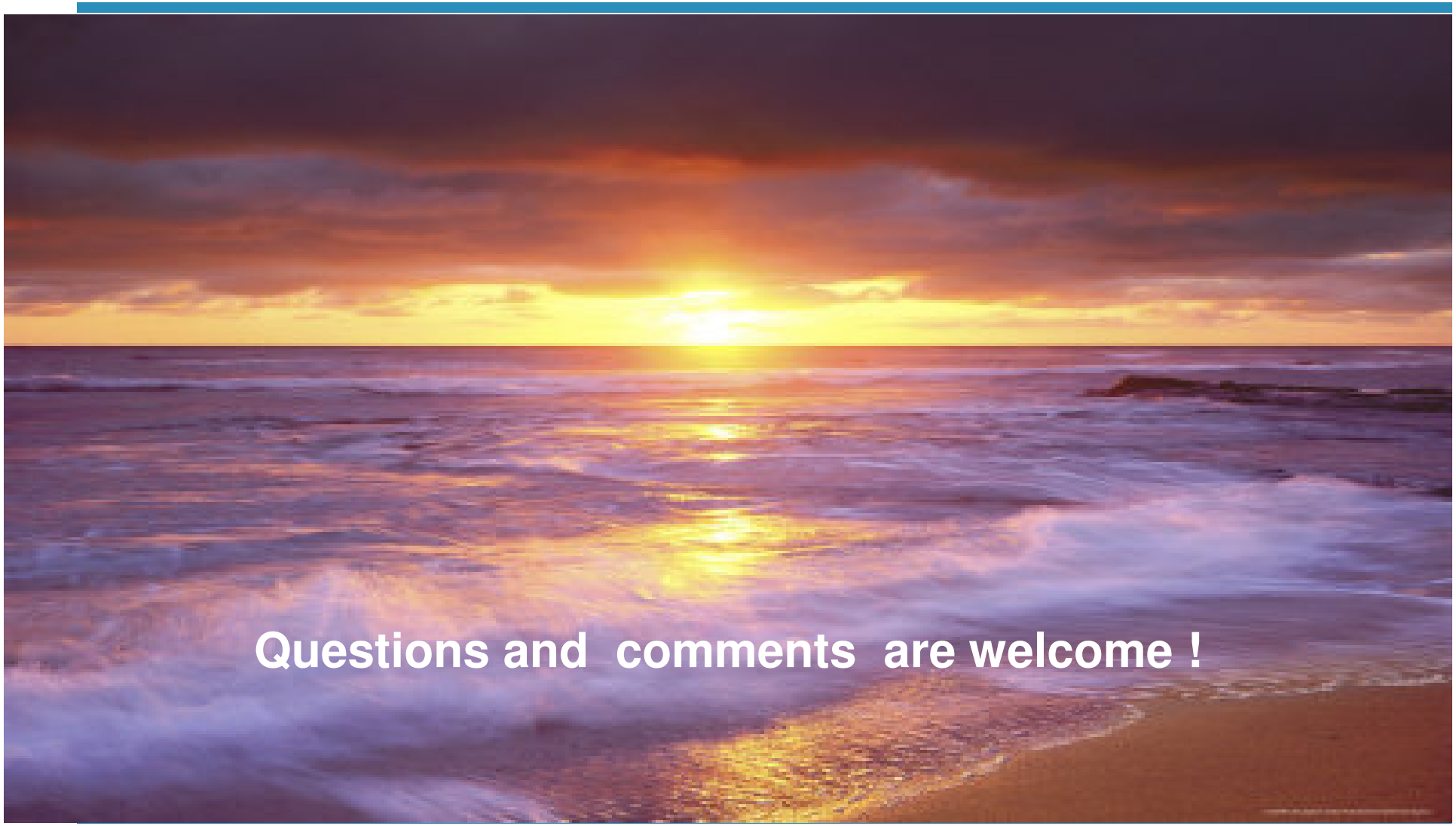
Obstacles include:

- Long lead times to draft and promulgate guidance documents
- Difficulty for stakeholders to reach consensus on harmonization efforts and agreements
- Delays inherent in transposition of agreements into laws and regulations
- Cultural differences can also present barriers to adoption of harmonized practices

Summary

- Innovation for devices has historically been linked with technological leaps
- The evolution of society, economic growth, communication and unmet clinical needs are the engines Innovation
- The boundaries between devices, drugs, biologics are getting blurred
- Suitability of existing regulatory regimes to accommodate review and assessment of risk of innovative products is being questioned
- Development of common assessment programs , quick standards review and adoption are key to control risks posed by innovation while ensuring rapid availability of novels therapies
- Cooperation between agencies and Industry is key to assess risk and establish or strengthen regulatory assessments
- A uniform approach will enable to pull resources and competences
- AHWP has a key role to play in this arena, jointly with GHTF

A Destination and a Vision for Harmonization

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