

The Role of Accredited Persons/Conformity  
Assessment Bodies in the Regulatory Process and  
Establishing Confidence in Performance of Accredited  
Persons/Conformity Assessment Bodies

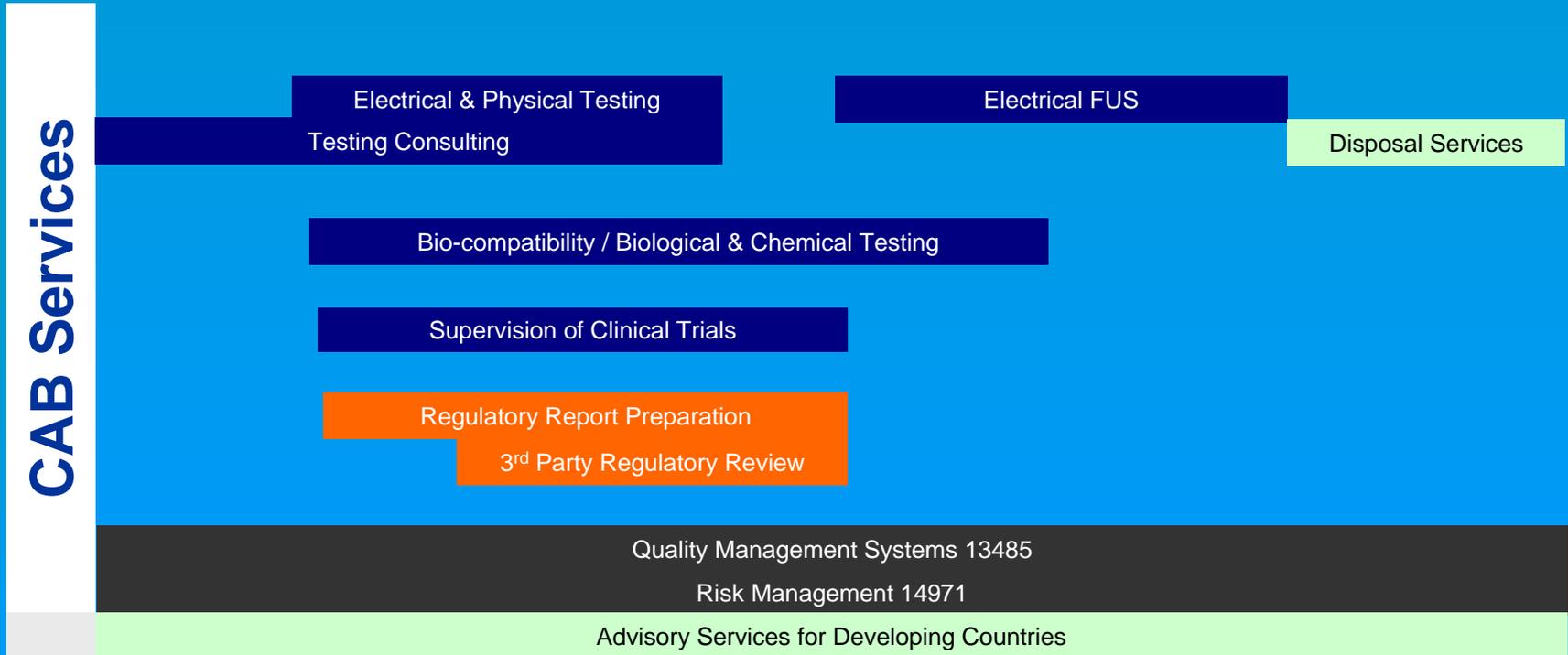
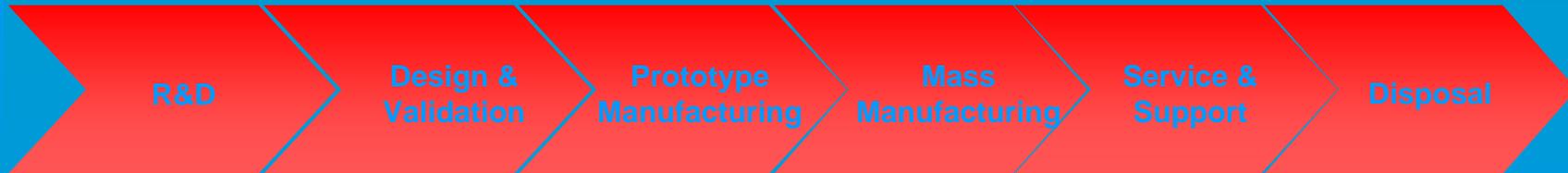
Presented by **Paul Chan**

# Agenda

What Conformity Assessment Bodies (CAB) offer to provide confidence to regulators and public that a medical device is safe for use.

# Overview of CAB Services

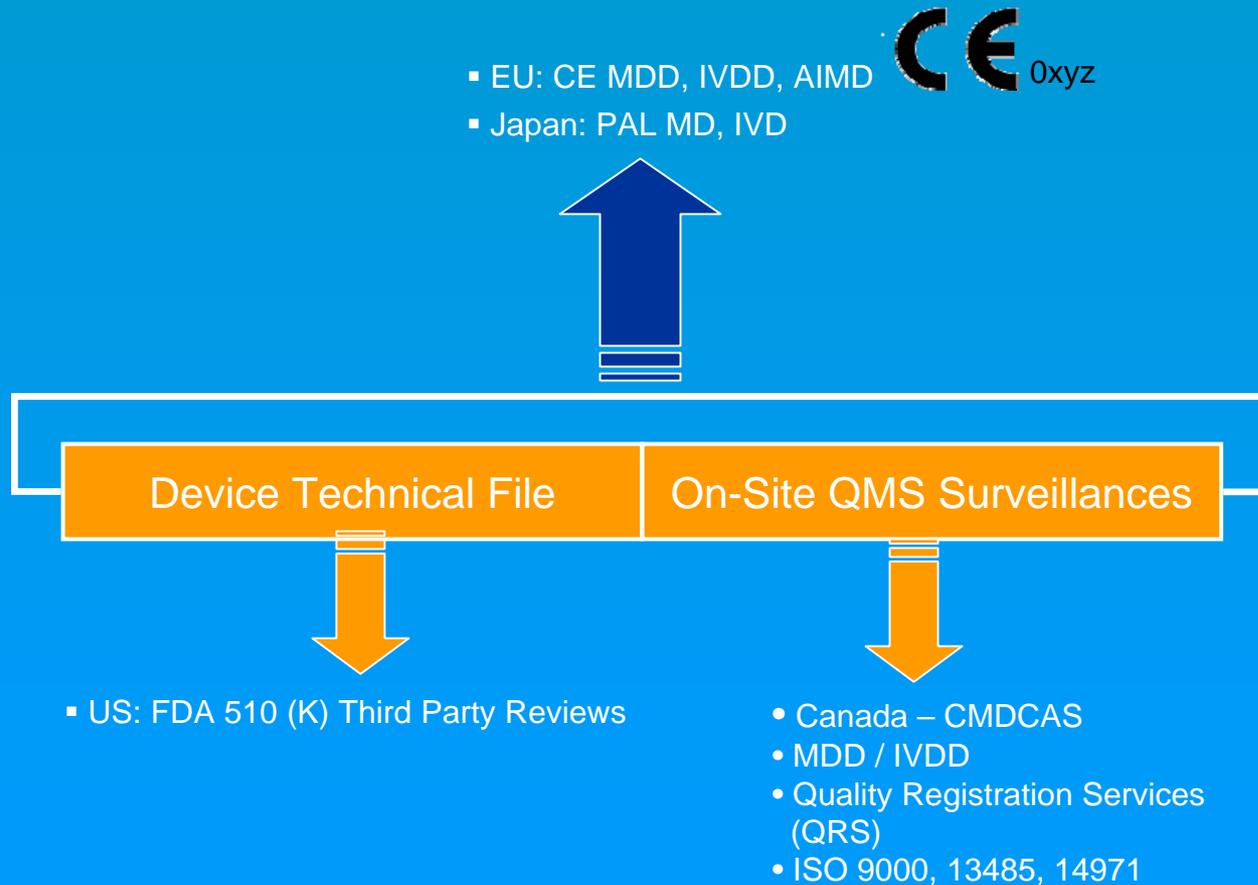
## Product Lifecycle



# Overview of CAB Services

Regulatory Services	Testing, Evaluation & Certification	Knowledge Solutions
<p><b>US:</b> FDA 510(k) Third Party Review Service; UL Mark for North America</p> <p><b>Europe:</b> CE Marking for MDD and IVDD</p> <p><b>Canada:</b> CMDACS Registration</p> <p><b>Japan:</b> PAL Certification for Class II Medical Devices</p> <p><b>Brazil:</b> INMETRO Certification</p> <p><b>China:</b> SFDA Registration/ CCC Certification</p>	<p>Product Safety Testing to IEC 60601-1/UL-60601</p> <p>Management System Registration: ISO 13485:2003</p> <p>Software Analysis: Conformance to IEC 60601-1-4</p> <p>Risk Management: Conformance to ISO 14971</p> <p>Electromagnetic Compatibility (EMC) – CB Test Reports and Certificates</p> <p>Conformance Certificate of Class I Medical Devices to MDD and IVDD Directives</p>	<p>Gap Analysis</p> <p>In-house Customized Training</p> <p>Public Seminars</p> <ul style="list-style-type: none"> <li>• Management System Registration: ISO13485:2003</li> <li>• Designing for Compliance to IEC 60601-1 (2nd Edition), IEC 60601-1 (3rd Edition)</li> <li>• FDA 510(k) Review</li> <li>• Understanding the MDD</li> <li>• Understanding the IVDD</li> <li>• Risk Management</li> <li>• FDA Requirements</li> </ul>

# CAB Scope/Limitation



# How CAB Facilitate Product Approval

US: **3<sup>rd</sup> party** conducts the primary review of the 510(k), then forwards its review, recommendation, and the 510(k) to FDA.

EU: Some MD and IVD require a **notified body**, to certify that the manufacturer meets the quality system and Technical File requirements before affixing CE marking and placing the device on the market.

Japan: All class II MD under the amended Pharmaceutical Affairs Law are required to obtain a certification of product conformance from a registered **3<sup>rd</sup> party certification body** (instead of MHLW) before marketing in Japan.

## CAB role in ASEAN countries ?

Local authorities under ASEAN countries may recognize 3<sup>rd</sup> party as CAB according to harmonized regulation.

CAB will on behalf of the harmonized regulation test, review, monitor the controlled products.

CABs can increase speed and efficiency of the medical device approval process: helping to bring innovative and quality devices to markets in order to support the health policies of various countries.

The major, developed markets of the world are increasingly using CABs for audits, inspections, and approvals for medical devices. And the system seems to be working well (limited incidents reported).

## CAB role in ASEAN countries ?

Not all CABs are equal. One need to make sure CABs have the technical capability to the job. Also need to work in collaboration with accreditation bodies to monitor the CABs and ensure that they operate with highest level of integrity. Those with higher levels of brand recognition tend to have more at stake and therefore can't afford to not maintain highest level of rigor in engineering judgment and integrity.

Manufacturers of medical devices want to sell their products in multiple markets. They will be reluctant to design products differently for just one market, particularly if they are small. Therefore, if you create new and unique requirements from the rest of the world, manufacturers may opt not to sell in your market.

## CAB role in ASEAN countries ?

Goal for CABs and manufacturers is global harmonization across the board (e.g. nomenclature, classification of devices, classification of CABs, audit procedures, product approval procedures, product requirements, etc.). One product, one test, accepted everywhere. Regulators need to work toward this goal, with support from CABs and manufacturers.

Thank You