SPEAKER'S BIOGRAPHY

NAME: SITI HAJAR BINTI YACOB

POSITION & AFFILIATION:

ASSISTANT DIRECTOR OF PRE-MARKET CONTROL DIVISON, MEDICAL DEVICE AUTHORITY (MDA), MINISTRY OF HEALTH MALAYSIA.

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TITLE OF TALK: ***How to Successfully Register Your Medical Device with MDA***

PROFESSIONAL EXPERIENCE

Assistant Director of Pre-Market Control Division

Medical Device Authority (MDA), Malaysia.

(25th October 2015- October 2024)

- **Regulatory Oversight**: Managed the evaluation and approval process for medical devices before they were marketed, ensuring compliance with national and international regulatory standards.
- **Device Classification & Risk Assessment**: Conducted thorough assessments and classifications of medical devices, focusing on risk analysis, safety, and efficacy.
- **Pre-Market Registration**: Led efforts in the registration and listing of medical devices, working closely with manufacturers and authorized representative to ensure proper documentation and adherence to regulatory guidelines.
- **Collaboration with Stakeholders**: Engaged with industry stakeholders, including medical device manufacturers, healthcare institutions, and international regulatory bodies, to align MDA's regulatory framework with global standards.
- **Regulatory Compliance and Coordination:** Responded to regulatory inquiries and provided expert guidance on submission deficiencies, ensuring timely and successful approvals.
- **Training & Outreach**: Conducted training programs, multiple workshops, seminars for industry players and Conformity Assessment Body (CAB) on regulatory

requirements, application processes, and pre-market control procedures, promoting awareness and adherence to best practices.

- **CAB Training Speaker:** Delivered expert-level training sessions for Conformity Assessment Bodies (CABs) on regulatory requirements, pre-market evaluation processes, and compliance standards, helping CABs improve their understanding and execution of assessments.
- **CAB Auditor & Inspection**: Conducted audits and inspections of CABs, ensuring their adherence to regulatory standards and operational procedures. Provided comprehensive reports with actionable recommendations to enhance their conformity assessment practices.
- **Development of Regulatory Guidelines:** Contributed to the creation and revision of pre-market regulatory policies and guidelines, ensuring that MDA's standards are up-to-date with global best practices in medical device regulation.

RESEARCH INTEREST

Siti Hajar Binti Yacob is a passionate and dedicated expert in **medical device registration**. **She** is a valuable asset to the **medical device or healthcare industry** and is committed to making a difference through innovative research focused on enhancing regulatory frameworks, improving compliance practices, and ensuring the safety and efficacy of medical devices.