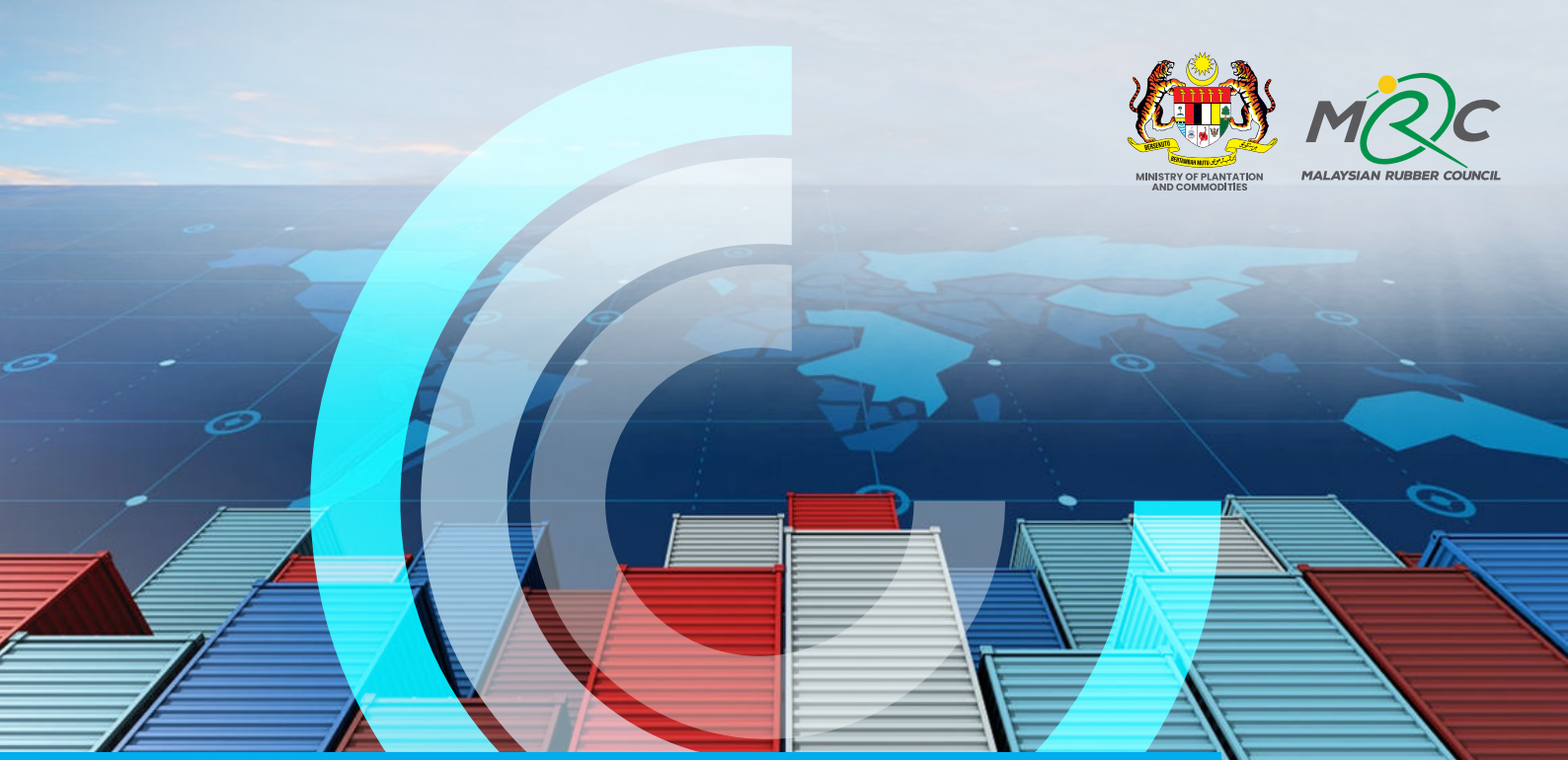

MINISTRY OF PLANTATION AND COMMODITIES

MALAYSIAN RUBBER COUNCIL

UNDERSTANDING AND MANAGING FDA IMPORT REFUSAL REPORTS IRR

20 Nov 2024
9am - 1pm

Microsoft Teams

SEMINAR FEE

RM60 MRC MEMBERS

RM150 NON-CESS & NON-MEMBER COMPANIES

Navigating the FDA's complex import regulations is critical for any business exporting goods to the U.S. The Import Refusal Report (IRR) is issued when products violate FDA standards, potentially causing significant disruptions to business operations and revenue. This webinar is designed to demystify the IRR process by providing a thorough understanding of the FDA's regulatory framework and the common causes behind import refusals. Participants will gain practical strategies for managing and responding to these refusals, ensuring their exports meet U.S. standards.

Geared towards compliance officers, importers, and regulatory professionals, this session covers the fundamentals of FDA import regulations and offers best practices to address and resolve issues that can lead to refusals. With a focus on minimising risk and enhancing compliance, the webinar will help businesses avoid future violations and reduce delays in the import process. By attending, you will gain the insights needed to safeguard your exports and keep your operations running smoothly in a competitive, compliance-driven landscape. Don't miss this essential opportunity to strengthen your FDA compliance strategies.

UNDERSTANDING AND MANAGING FDA IMPORT REFUSAL REPORTS (IRR)

Speakers

Lim Beng Ee
Co-founder of Complizen

Cem Guler

Mert Zamir

Melissa Hall
Founder and Principal Consultant of Statera Regulatory Consulting

Mary K. Moore
President and Principal Consultant of MKM MEDDEV Strategies LLC

Who Should Attend

- Legal and Regulatory Advisors
- Export Managers
- Supply Chain Managers
- Compliance Officers
- Malaysian Business Professionals

Following this session, attendees will:

+

Be familiar with legal and regulatory framework

Identify common grounds for import refusal

Be proficient in the IRR process

Develop strategies for managing and responding to IRRs

Programme

8.30 am Registration

9.00 am Welcoming Remarks by MRC

9.15 am **Introduction to FDA (U.S. Food and Drug Administration) Import Refusal Reports (IRR)**

- FDA's role in regulating medical devices
- Definition and classification of medical devices
- Type of premarket submissions and 510(k) process (with a focus on gloves)
- Utilizing FDA resources

QMS Basics

- Defining Quality Management System (QMS) and identifying components
- Process approach for QMS and sources of requirements
- Compliance vs. conformance
- QMS requirements per ISO 13485:2016 and US FDA 21 CFR 820

10.45 am Morning Break

11.00 am **Import Refusal Reports (IRR) Management and Case Studies**

- Detailed IRR process overview
  - What is an Import Refusal?
  - Notification Process
  - Options for Refused Products
  - Next Steps if 90 Days Pass
  - Appeals & Extensions
- Case Studies

12.15 pm **Practical application with Complizen**

1.00 pm End of Programme

For More Information, Please Contact:

E-mail: najwa@myrubbercouncil.com (**Siti Najwa**)
Tel: +6014-2232388 / +603-27822100

www.**myrubbercouncil**.com
MYrubbercouncil