

# **Seminar Overview**

## **Group D**

Group D-Seminar Overview  
Bangkok, Thailand June 2005

# Topics of Discussion

- **Asia Pacific Regulatory Overview**
- **Critical Success Factors**
- **Challenges**
- **Wish list**
- **Take Home Message**

# Countries of Discussion

- China
- Hong Kong
- Japan
- Korea
- Malaysia
- Singapore
- Thailand

# Critical Success Factors

- Harmonize regulatory requirements in AP
- Recognize other countries approval
- Simplified common STED format
- Common Adverse Event Reporting
- Internationally recognized auditing system

# Challenges

- Standardization of classification
- Type testing + site audit requirements
- Common language
- National requirements + GHTF requirements
- Changing of current/existing regulations
- Hefty regulation charges
- Delayed in product introduction to market

# The way forward

- Mutual recognition agreements
- Common Directives
  - European Union
- ASEAN Harmonization

# **Wish list**

- One Medical Device**
- One submission**
- One Approval**

# **World wide**

# Take Home Message

- Do not re-invent the wheel



# **Thank you**

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