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TSA Screening Compliance: Recommended Practices and Considerations for Manufacturers

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Screening requirement may change the transportation process

- Screening time & ambient temperature may impact packaging performance
- X-ray screening technology may adversely affect product quality
- Pallets may not be rebuilt properly after inspection
- How to managing “false positive” screening results
- Preferred air carrier may not accept unscreened unit load devices

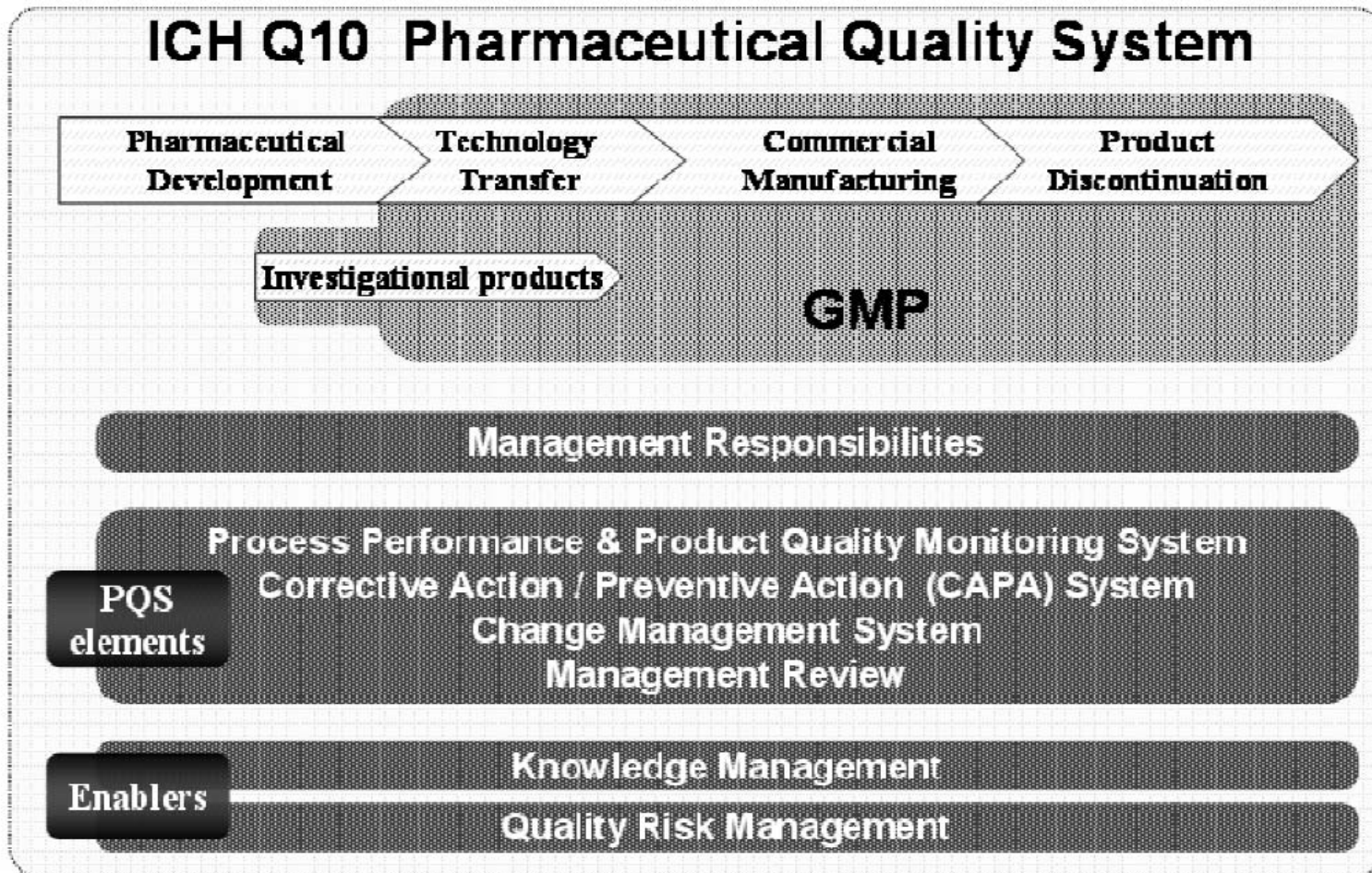
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Process changes must be managed



Reference: ICH Pharmaceutical Quality System Q10 (2008)

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Certified cargo screening facility (CCSF)

Advantages

- Decreased delays, shipper controls the screening process
- Ability to build bulk configurations / maintain packaging integrity
- No investment needed to purchase screening equipment

Disadvantages

- Cost to implement facility and chain of custody standards
- Must have a facility that can be secured
- Shipper becomes regulated by TSA



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Third party screening

Advantages

- Possible lower start-up cost
- Reduced time to compliance

Disadvantages

- Package may be opened in the event of a “false positive” screening alarm
- Product could be subject to X-ray screening
- Service provider may not consider cold chain requirements
- Additional time in the supply chain will be needed
- Process and packaging may require redesign and/or requalification



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Active unit load devices (ULD)

- ULDs are not considered the “largest piece level”
- Put product boxes in an over pack (largest piece level) to expedite screening
- Container / dry ice bunker door is sealed with tamper-evident technology
- Tamper evident tape should not interfere with the functionality of the container
- Check if the air carrier will accept “unscreened” containers

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X-ray screening

For product sensitive to X-ray radiation, several options should be considered:

- Confirm with airline if x-ray or another form of screening will be used
- Become a CCSF or define screening method with service provider
- Use a cover to protect the product from x-ray (special documentation required)



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PDA Pharmaceutical Cold Chain Interest Group Task Force

Objectives:

- Support CCSP implementation while respecting security requirements
- Promote education and the exchange of information
- Create written industry guidance

**Recommended Best Practices for Manufacturers of
Temperature Sensitive Products to Comply with TSA
Cargo Screening Requirements**

Guidance produced by the PCCIG TSA Cargo Screening Task Force
for the PDA Pharmaceutical Cold Chain Interest Group

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PDA recommended practices

- Shippers should consider becoming a Certified Cargo Screening Facility
- If using a third party screening service, discuss:
 - Ambient conditions in which the product will be screened
 - Electronic trace detection alarm resolution (may involve physical search)
- Place the product boxes in an over pack and tender as one piece
- Confirm air carrier's policy regarding accepting "unscreened" containers.

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Thank you for listening!

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