

Thermal Packaging and Temperature-Controlled Container alone is not enough!

Bourji Mourad BRU - 25 Sep 2025

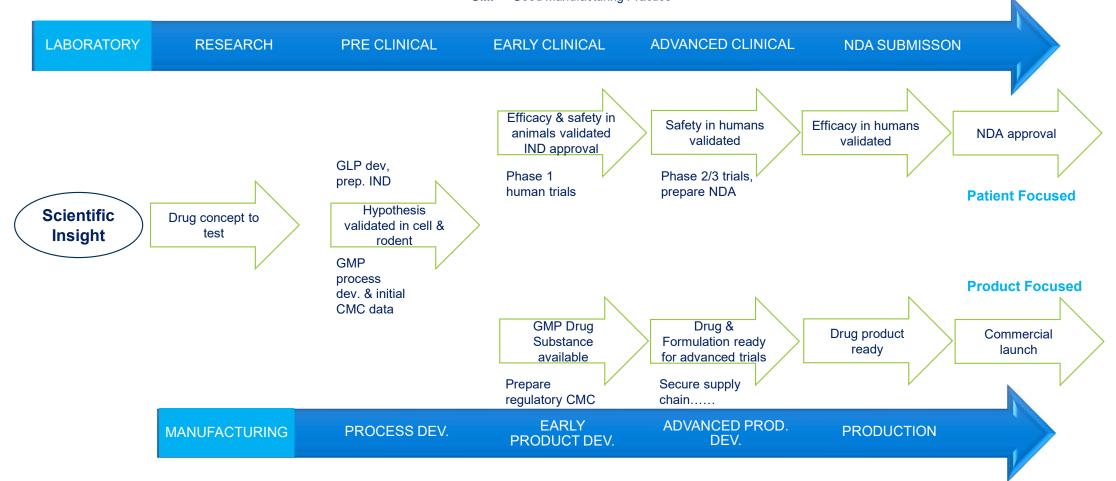
THERMOSAFE



The Journey of a Drug

GLP = Good Laboratory Practice **IND** = Investigational new drug **GMP** = Good Manufacturing Practice

CMC = Chemistry, Manufacturing, and Controls
NDA = New Drug Application



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Regulations – Guidance - Compliance

























Bulk Packaging Solutions (to name a few)



























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Larger Equipment for protecting Temp. Sen. Cargo









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Selection & Qualification of Packaging Solution



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Decision Process & Criteria for using new Packaging Solution

PEACE OF MIND

Does the packaging solution fulfil Regulatory & Product Quality requirements?



RELIABILITY

Does the packaging solution allow user to Deliver on Time and in Full?



CRITERIA

Does the packaging solution fulfil all Other Requirements?









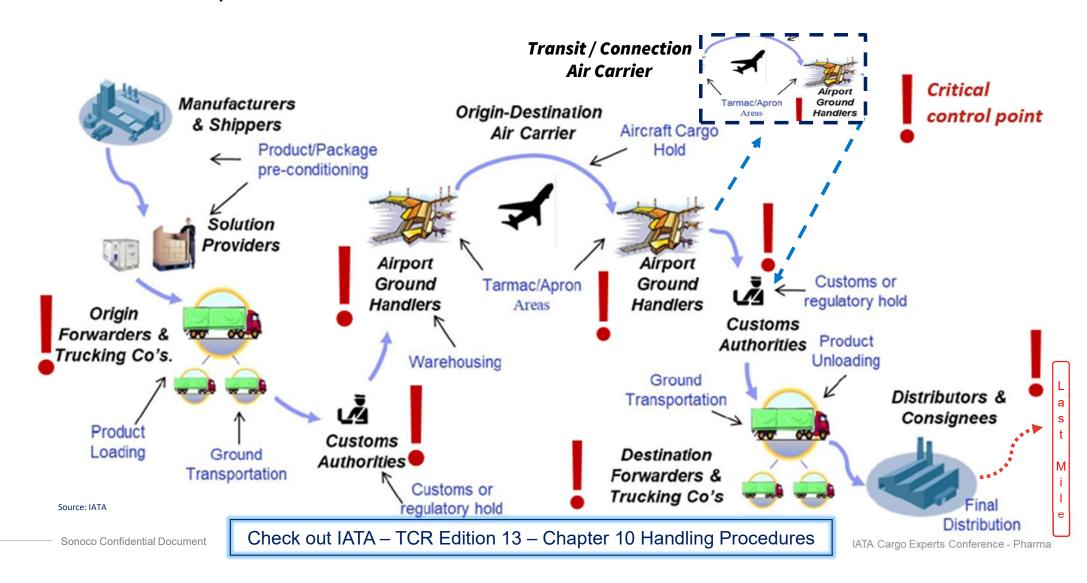




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Stakeholder, Critical Control Points - ie: Cold Chain



Cold Chain



Cold Chain is considered as a Science, a Technology, and a Process

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THANK YOU



