



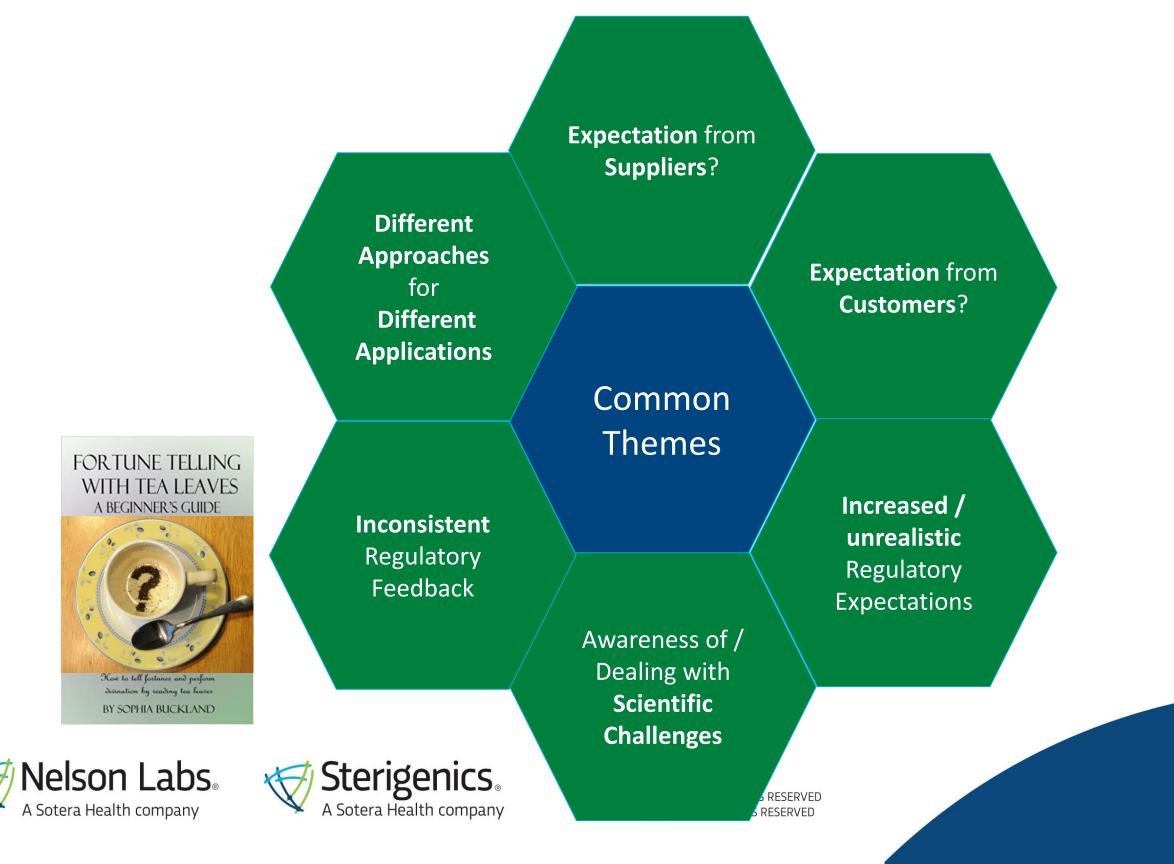
Common Themes and Challenges in Large Volume Parenteral Packaging Qualifications The need to create an "LVP Interest Group"?



Common Themes for LVP's







Common Challenges for LVP's





Common Challenges for LVP's

Extremely low levels of Extractables & Leachables Qualification

The AET Gap: How low can you go VERSUS how low should you go?

How to deal with the AET Gap?

How to design multi-functional Simulation Studies

Regulatory Acceptance of Simulation Studies

Consequence of Low AET: high number of unknown compounds that are above the AET level

Consequence of Low AET: Toxicological Assessment become very large, additional request Tox Data

How to deal with Material Changes?

To what extent does **Secondary Packaging** need to be included in the overall qualification process?

And what about qualifying the components / DP for n-Nitrosamines?

Where is the delineation between a Medical Device and a Pharma Container, potential consequences for the Study Designs and Qualification Process?

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LVP "Interest Group": a Value Proposition?





Observations

"General" Mission Statements of Pharmaceutical companies

- Develop Safe, Effective (and Innovative) Drug Products
- For the Treatment of (life threatening) Diseases
- Safeguarding Global Health

The reality for LVP's typically is:

- Often not Really Innovative
- > From a Pharma Perspective:
 - Lower Margin
 - High Volume Drug Products
- Cost Efficiency is Important!





MISSION Statement

GUIDED BY A RELENTLESS FOCUS

(HEARTFELT ADJECTIVE)

ON GUALITY, (ANOTHER CLICHE)

WE WILL STRIVE TO

(LONG-WINDED PHRASE)

DELIVERING
(BIG ASPIRATIONAL WORD)

SLIDE 1 OF 42



Cost versus Safety of an LVP Packaging System

Lower Cost Drug Products Lower Margin Drug Products

LVP

High Safety Requirements
High Level of Regulatory Scrutiny
Large E/L Testing Budgets

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"We're not reinventing the wheel. We're reinventing the process of inventing the wheel. It's completely different."

Can the overall Safety Qualification of an LVP be done in a more "cost effective" way?

One way that could be explored: Consideration for an "LVP Interest Group"



"Ralph is doing a preliminary study of re-inventing the wheel."







Sharing Experience Information

Sharing Ideas

Interaction with

Research

White papers | Articles

Best Practices

Medical Device us Pharma Container

LVP Interest Group

Networking Collaboration

PDA

Regulatory Feedback

Lessons Learned

Upcoming Issues (e.g. Nitrosamines)

7ips & Tricks

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Solutions

THANK YOU!!!







Questions?



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