



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

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Common Themes for LVP's





Common Challenges for LVP's



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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?



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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:

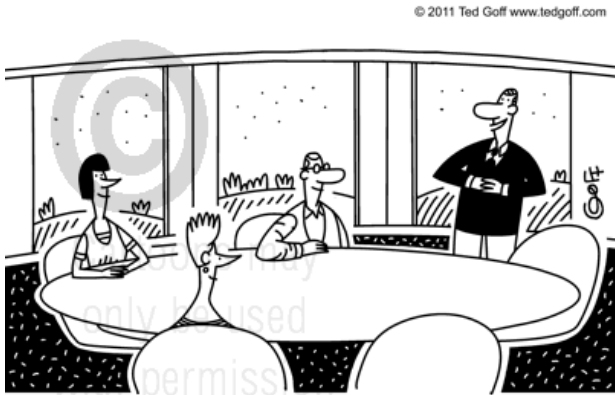
- Often not Really Innovative
- From a Pharma Perspective:
 - ❖ Lower Margin
 - ❖ High Volume Drug Products
- Cost Efficiency is Important!



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Cost versus Safety of an LVP Packaging System



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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."



THANK YOU!!!



Questions?



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