SINGLE USE TECHNOLOGY

by Rommelag

Healthcare Customer Event | Lyondellbasell
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Practical Use and Innovation

Summary / Key Message / Literature

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ROMMELAG ENGINEERING

Aseptic bottelpack filling systems and BFS inspection systems

ROMMELAG CMO

BFS contract manufacturing of liquid and semi-solid products

ROMMELAG FLEX

Innovative containment solutions

ROMMELAG SERVICE

Individualised aftersales and Pharma Service

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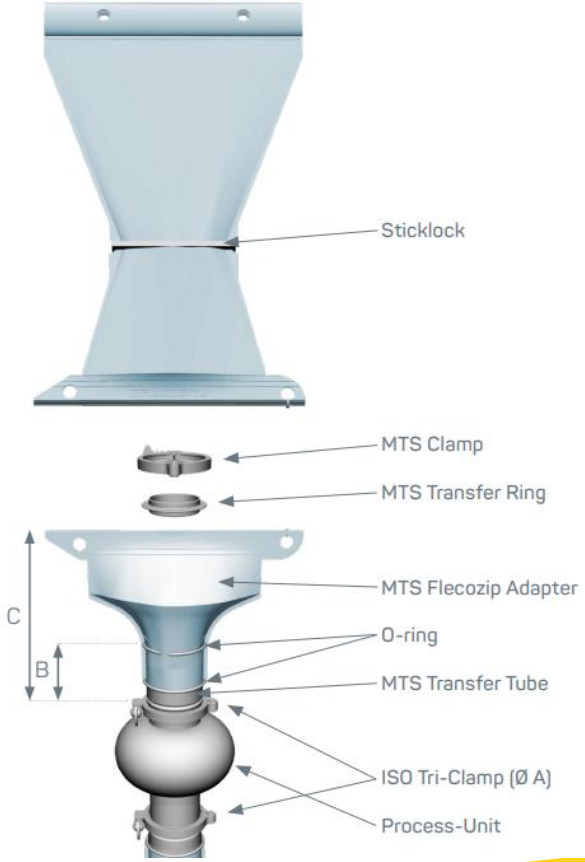
FLEX

MAIN APPLICATIONS IN THE PHARMACEUTICAL INDUSTRY

Flexible Isolators for i.e. contained dispensing

Material **T**ransfer **S**ystem for contained bag charging & discharging



Vaccum Bags, for contained processes under pressure

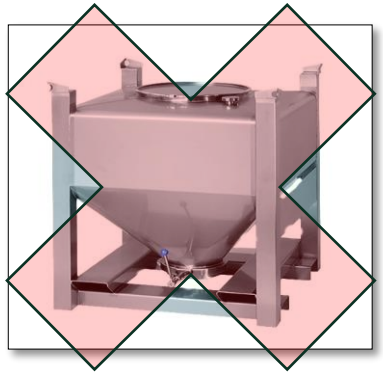
ROMMELAG SINGLE USE AND SUSTAINABILITY

General Trend

Do we have a conflict ?

General Pharma Trend

MUT



SUT

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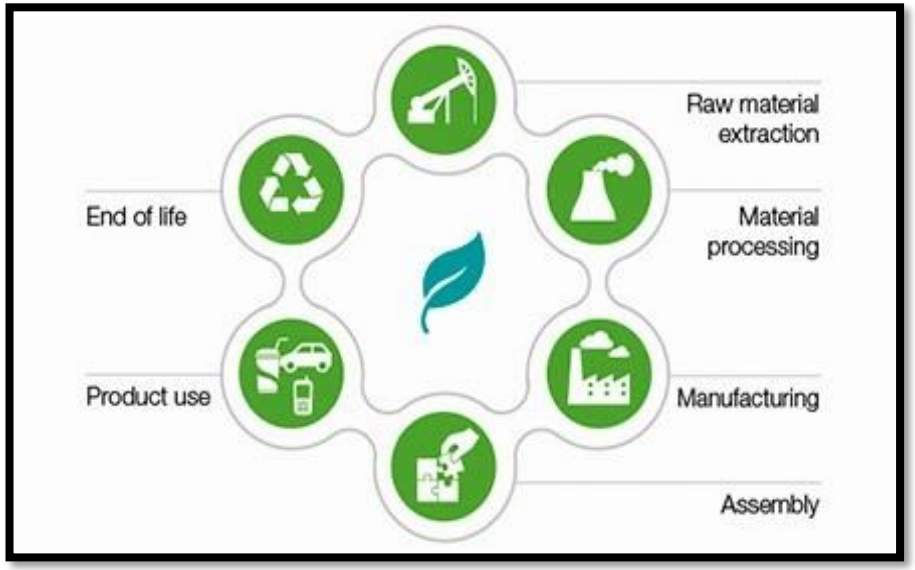
The Answer : LCA Study

LCA (Life Cycle Assessment) : Cradle to grave study

ISO LCA Standard

ISO 14040:2006
ISO 14044:2006



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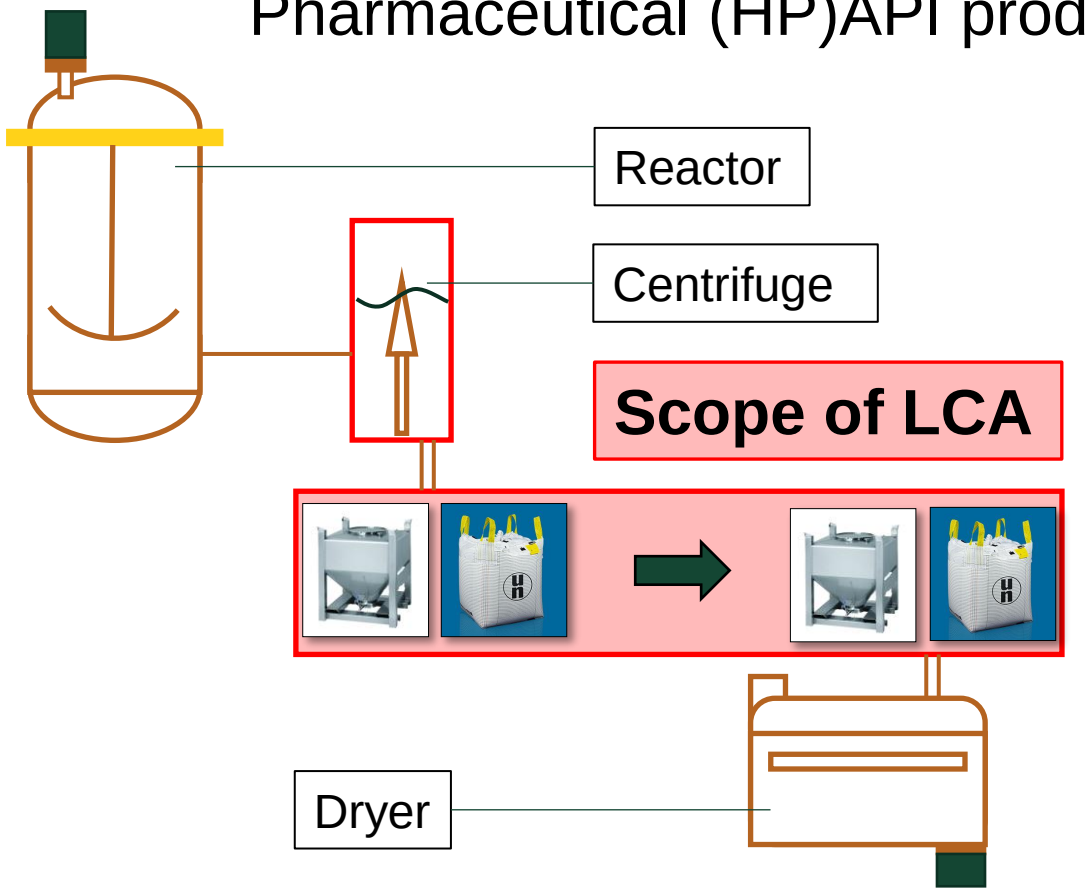
Pharmaceutical (HP)API production



LCA Study

Stainless Steel IBC

Single-Use FIBC

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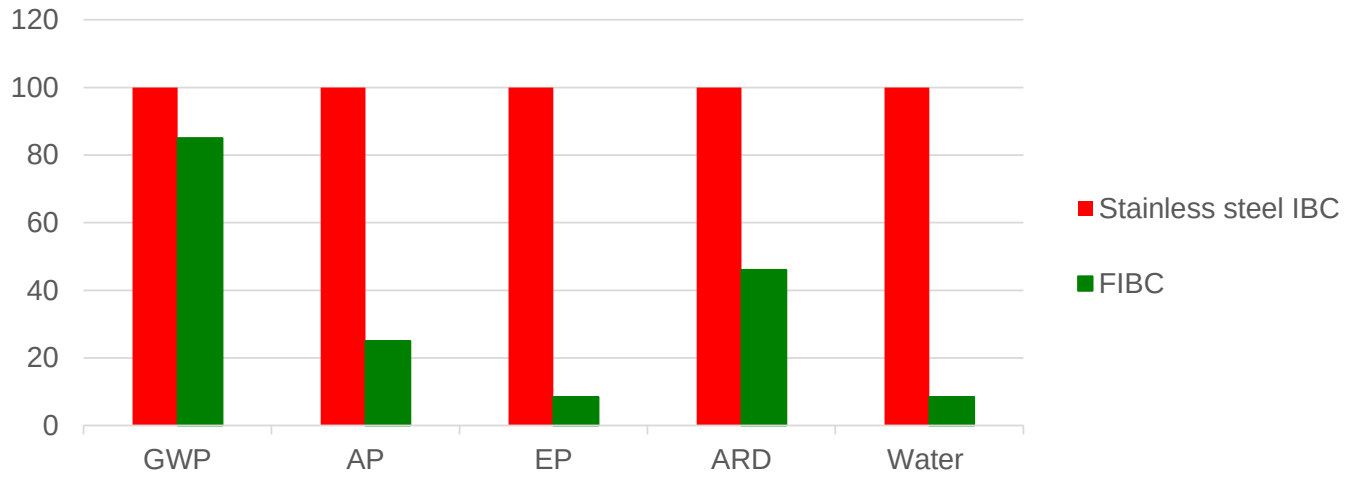
Direct Impact Comparison:

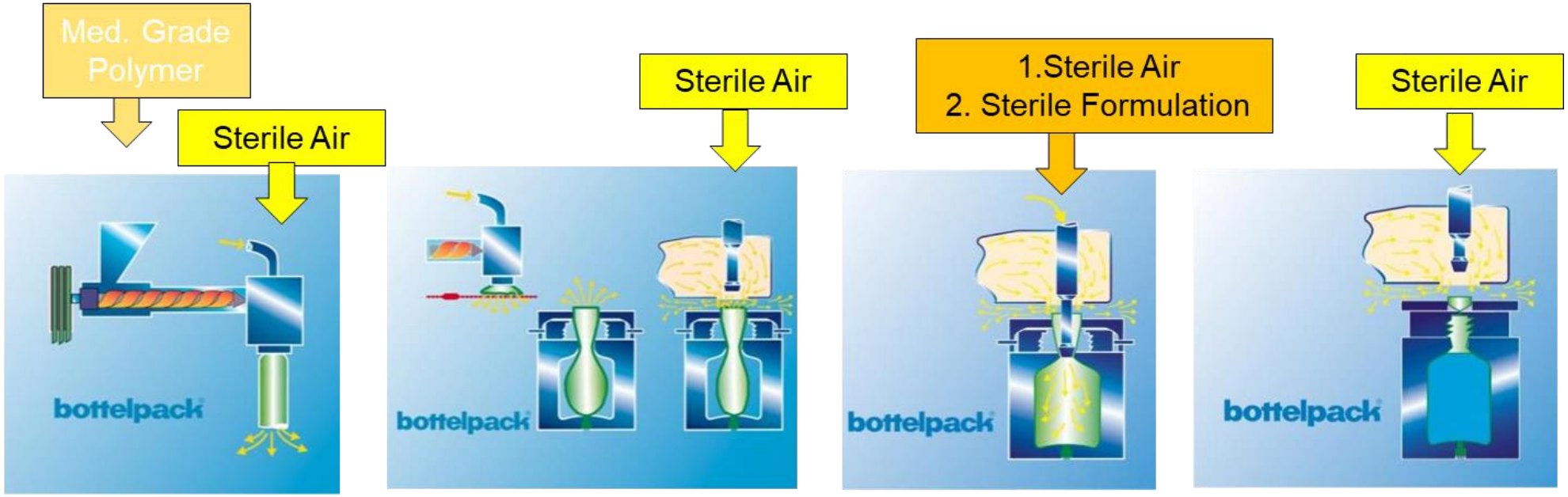


Impact Categories :

- **GWP** (Global Warming Potential)
- **AP** (Acidification Potential)
- **EP** (Eutrophication Potential)
- **ARD** (Abiotic Resource Depletion)
- **Water** (Water Footprint)

Important Note: Datas valid for equipment used in the pharmaceutical (HP)API production /1/

Process Overview (cycle process) – What is BFS?



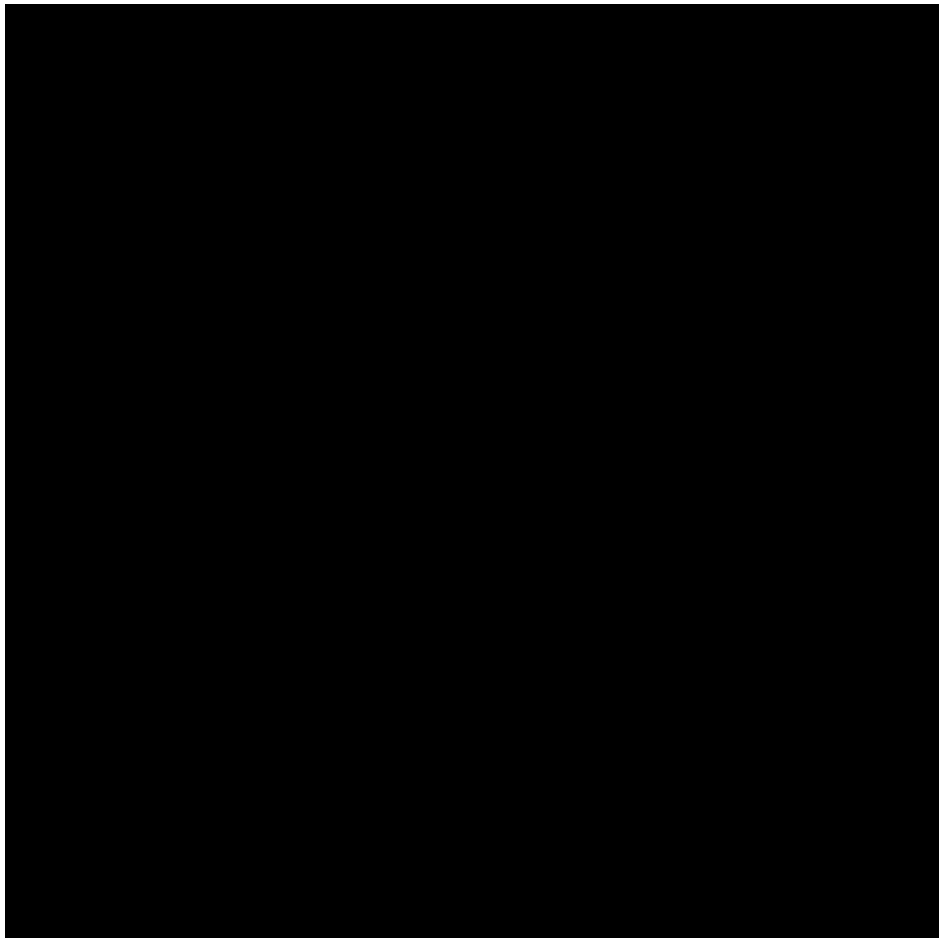
Melting polymer & extrusion of parison with sterile air

Transfer in mold and cutting of parison with sterile air overpressure

Container blow forming with sterile air or vacuum followed by filling

Container sealing

bottelpack® - how it works in general /2/3/4/5/



Link to BFS Process for Ampoules - YouTube

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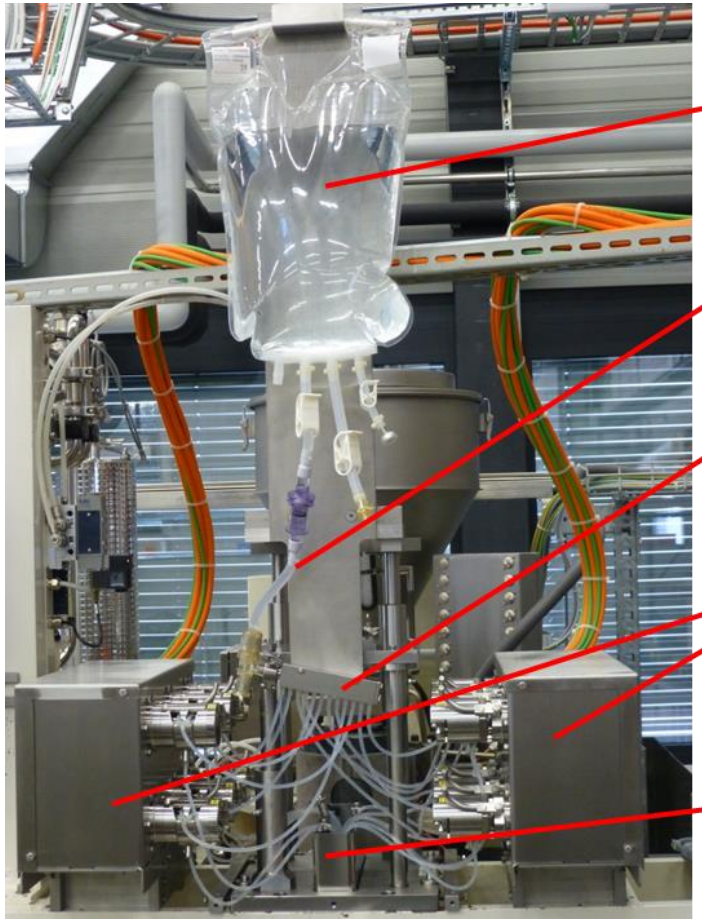
BOTTELPACK® WITH DISPOSABLE FILLING SYSTEM (DFS)

Conceptual design

- Optional dosing system to the **bottelpack®**
- Dosing of the DFS works with an peristaltic pump in place of time-pressure dosing
- Use of preassembled sterile disposable components in the product leading way, high sterility safeness
- Short reaction time, less time for construction activities by change of filling volume
- Design for small product batches from 100 ml to 5-10 litres and / or high-priced products (special in pre-clinic and clincial phases)
- Lower costs, lower barriers to entry for potential customers interested in a technical filling – quicker entry into the **bottelpack®** technology, more flexibility

BOTTELPACK® WITH DISPOSABLE FILLING SYSTEM (DFS)

Layout / overview main components



bag

Disposable adapter with sterile connector and connector for SIP

Manifold with preassembled disposable filling line

Pump unit, consisting of max. 12 peristaltic pumps on 312 – dimension 300 x 300 x 450 mm

Mandrel unit

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BOTTELPACK® WITH DISPOSABLE FILLING SYSTEM (DFS)

Benefits

- Cleaning and cleaning validation costs (cross contamination) are greatly reduced when compared to stainless steel installations
- Lower cost, reduction in the amount of product required due to the elimination of sterile pipe work (high-priced products, small batches)
- Less format depending parts needed to cover a big width of different fill volumes
- Easy steps for conversion, high sterility safeness
- Independent of certain manufacturers of disposable parts – works with different systems
- Ecological footprint related to a classic machine cleaning incl. cleaning validation is smaller
- Advantages in development = speed, few cavities, no cleaning effort good for freezing / thawing processes (biological drug products)

BOTTELPACK® WITH DISPOSABLE FILLING SYSTEM (DFS) PRACTICAL USE /6/7/8/9/

rhDNase (Pulmozyme, Genentech)

4 mg/ml formulation, 37°C for 15 min.
Visual inspection, ELISA, CD, UV SEC, activity assay

Fully active, no aggregates, no permanent changes to conformational states
2-year refrigerated stability verified

EPO (Erytropoetin, Epoetin-Beta)

200 mycl with 500 bis 10`000 I.E.
BFS-Process with Purell 3020D
Visual inspection, ELISA, CD, UV SEC, activity assay

Fully active, no aggregates, no permanent changes to conformational states
2-year refrigerated stability verified

Attenuated Live-Virus Vaccines (flu vaccine and Rota-Virus vaccine)

0.2 and 2.3 ml
BFS-Process with Purell 1840H

No statistically significant differences in stability compared to conventional filled market products (glass & LDPE container)
2-year (flu vaccine) & 1-year (Rota-Virus) stability verified

Recombinant RSV F Vaccine (Novovax)

The stability profile of RSV F vaccine under accelerated and intended storage conditions is comparable to the profile in glass vials and syringes

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PRACTICAL USE AND POTENTIAL INNOVATION

Apiject

We bring together Blow-Fill-Seal and injection-molding technology so that pharmaceuticals and vaccines can be fill-finished in single-dose prefilled injectors at any scale.

ApiJect | Single-Dose, Prefilled Injectors using BFS Technology

UNITHER invests 68 million euros in the innovative project: Euroject® : Unither Pharmaceuticals (unither-pharma.com)

Both companies use blow-fill-seal technology as a foundation for their product development

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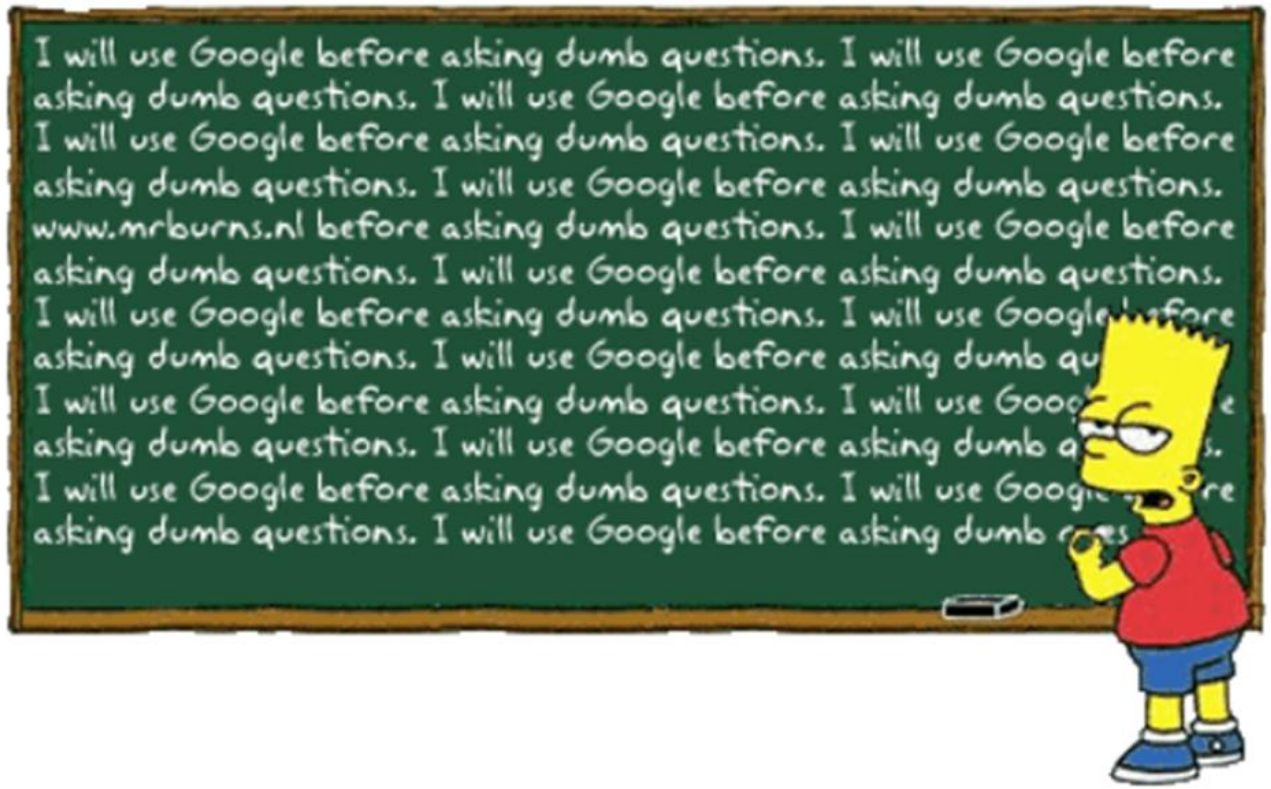
SUMMARY / KEY MESSAGE

- *Rommelag Flex's solutions ensure the highest personal and product protection when handling high potent APIs in the pharmaceutical industry.*

- *A disposable fill systems working with blow-fill-seal (BFS) technology would permit products fill (with limited volumes or small batch sizes) that could not normally use by BFS.*

QUESTIONS?

I will use Google before asking dumb questions



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