

CHALLENGES IN BIO-PHARMACEUTICAL SECONDARY PACKAGING PROCESS

生物制药后道包装中的挑战

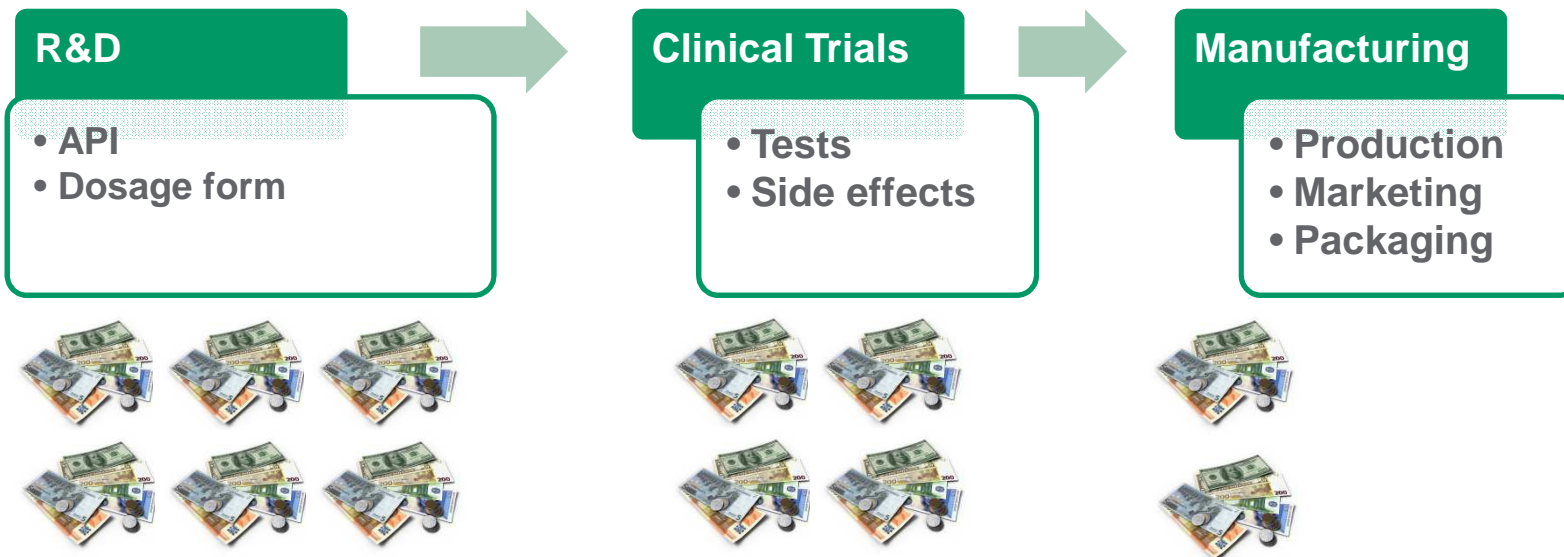


Nicola Vella, General Manager KMS Shanghai
Chengdu, 21st September 2017

Brundtland Commission, 1989

World Commission on Environment and Development

„Sustainable development is the development that meets the needs of the present without compromising the ability of future generations to meet their own needs “

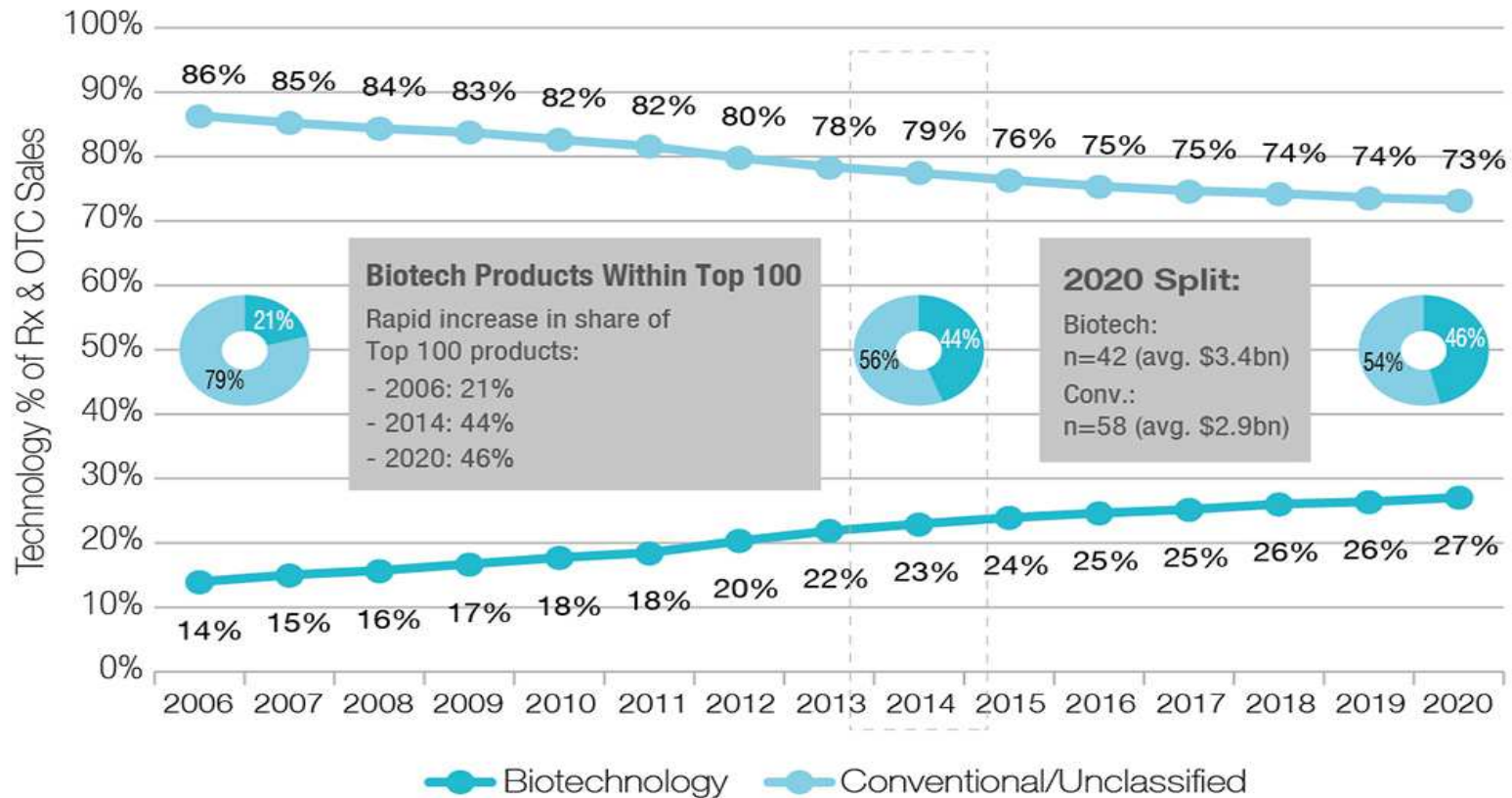


**Does your packaging
fulfill the current
and future
requirements ?**



DEVELOPMENT FOCUS CHANGING

WW Prescription Drug & OTC Pharmaceutical Sales Fig. 4
Biotech vs. Conventional Technology (2006–2020)



Source: EvaluatePharma World Preview 2015

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COMPLEX PRODUCTS

Simple Vial, Product



Milky Liquid



Turbid Liquid



Lyophilized Powder



Hyaluronic Gel Pre-Filled Syringe



COMPLEX CONTAINERS

Pre-Filled Syringes



Micro Cartridges



Auto-Injector Pens



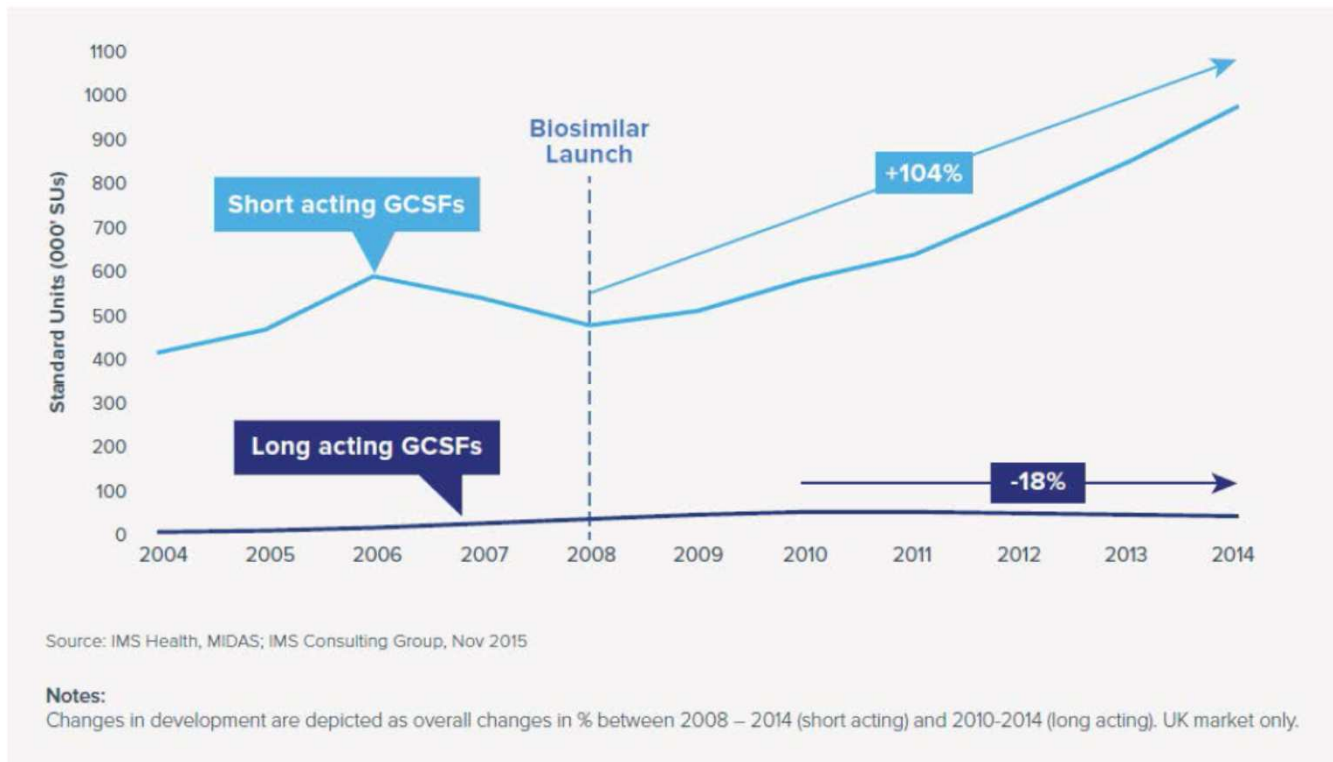
Inhalers



Wearables



COMPLEX MARKETPLACE



TREND SUMMARY

- **SUBSTANTIAL GROWTH CAN BE SEEN IN THE BIOPHARMACEUTICAL INDUSTRY**
- **THE DISEASE STATES AND THERAPIES ARE INCREASING IN COMPLEXITY**
- **THEIR PRODUCTS AND THEIR CONTAINERS ARE INCREASING IN COMPLEXITY**
- **THEIR DEMAND IS FOR SMALLER PATIENT POPULATIONS AND IS PERSONALIZED**

Maintaining an eco-friendly business often conflicts with driving down costs, but sustainable packaging may provide the solution that pharmaceutical companies are looking for

Sustainable packaging design is an increasingly important consideration for pharmaceutical companies. Trends towards increased home administration of therapies drive the need for unit dose and compliant consumer packaging. Approvals for new biopharmaceutical products have dramatically increased the demand for reliable, safe, cost-effective and uniquely identifiable packaging. With the surge and increased acceptance of pre-filled syringes, syringe/vial kits and alternative drug delivery systems, new and innovative packages are being developed, with highly effective patient safety and product protection features.

Eco-Friendly and High Performance

The goal of sustainable packaging is to reduce the environmental impact of a product's package. Eco-friendly package considerations go well beyond recyclability. Consideration must also be given to the amount, type and biodegradability of the material; overall package volume and weight reduction, to minimise transportation energy; printability of the material to eliminate separate labels; and even the amount of energy required for forming the package. These 'green' considerations are sometimes contrary to the unique needs of parenteral package features, including better product protection, increased billboard space for patient compliance, tamper evidence, and unit dose packaging trends. A well designed green parenteral package starts with package material selection. Eco-friendly materials are renewable, biodegradable, recyclable, and require relatively little energy for production and recycling. Laminated materials which are common in packaging also present challenges in recycling. Most must be physically separated before recycling, which is not always feasible. Paper has the inherent advantage of coming from a renewable resource. It is also commonly recycled, and can be directly printed on, thus eliminating the need for separate labels. Paper packages are formed easily by folding, which uses much less energy compared to plastic packages that require heat for the forming process.

Higher Production Efficiencies

The KMS NeoTOP top load cartoning solution is an example of eco-friendly materials creating a lower total cost of ownership. When compared with a blister system, this solution clearly demonstrates a higher degree of eco-friendliness and performance, with a lower overall cost.

- The NeoTOP creates a lower volume package. Blister systems require more ‘space’ between products, and using the NeoTOP can save up to 40 per cent compared to blisters.
- It provides a ‘monoblock’ packaging system. An additional cartoning system is required along with the blister systems
- No costly thermoforming process required
- Fewer personnel required to run a ‘monoblock’ system
- The package (carton and partition) is made of eco-friendly ‘mono-material’
- Higher machine efficiencies

A key principle in this example is ‘the more product in a folding box, the greater the cost savings’.

Accomplishing Specific Packaging Goals

Parenteral packages also need to provide product protection and crush resistance, minimise package volume, and provide tamper evidence. The FDA has stated that the manufacturer is responsible for their products shipping safely through the distribution chain to the end user. An eco-friendly parenteral package can be engineered to create structural strength, while nesting the product and incorporating tamper-evident opening features. Increased structural integrity of a paperboard package can be accomplished by utilising paperboard stiffening members. The partition which cradles the product can also provide stiffness to the package if it is bonded to the package itself. Due to the increased stiffness, overall material thickness can be decreased. This is called ‘downgauging’ or ‘lightweighting’. For paperboard cartons, partitions can be bonded into the package using hot-melt adhesive – a process that can be easily automated.

Eco-Economical

The reality is that any package design that adds significant expense is destined to fail. Overall cost can include package material, labour and shipping costs. Paperboard blanks can be shipped flat to minimise volume for inbound shipping, then formed, glued, and filled using automation equipment. State-of-the-art machines are capable of erecting cartons, gluing partitions, and filling products at high speeds. Machines with a high degree of flexibility can produce different package formats with quick changeovers and high overall equipment efficiency (OEE). This further contributes to sustainability by reducing plant floor space, resulting in less energy required for heating/cooling, and even construction and building materials.

Conclusion

Sustainable packaging is attained by utilising an engineered approach that addresses the entire packaging and product life cycle, not merely the package itself. Paper-based engineered packages can offer significant advantages in achieving an eco-friendly and a high performance package while providing the least total cost of ownership.
