ALMAC

Partnering to Advance Human Health

CLINICAL SUPPLY

PACKAGING FOR BIOLOGICAL PRODUCTS

PART 2 OF THE CLINICAL SUPPLY KNOWLEDGE SHARE SERIES

Almac Clinical Services

Understanding and **Delivering** your Global Clinical Supply Chain

CLINICAL SUPPLY PACKAGING FOR BIOLOGICAL PRODUCTS

eBOOK CONTENTS

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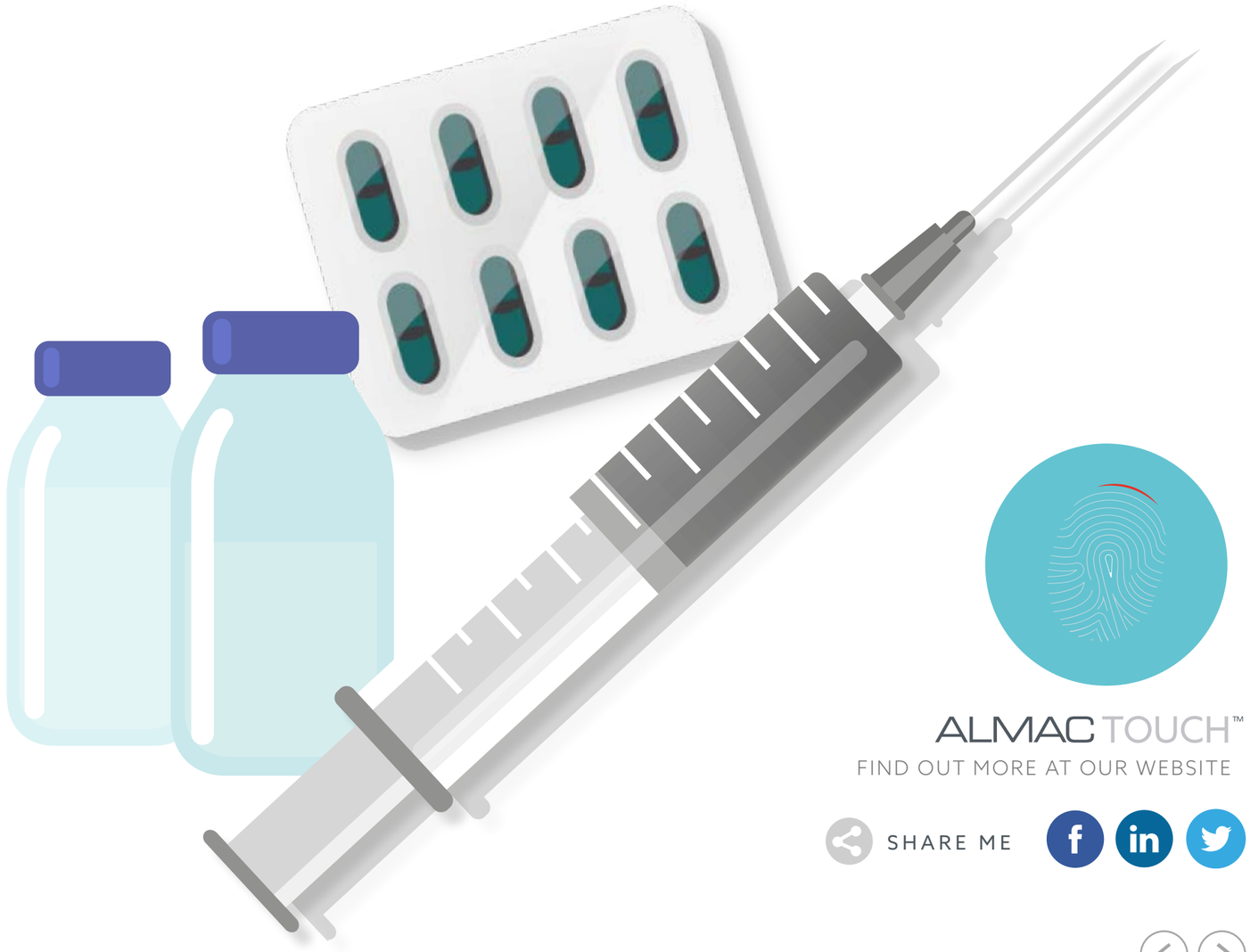

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THE RISE OF BIOLOGICS

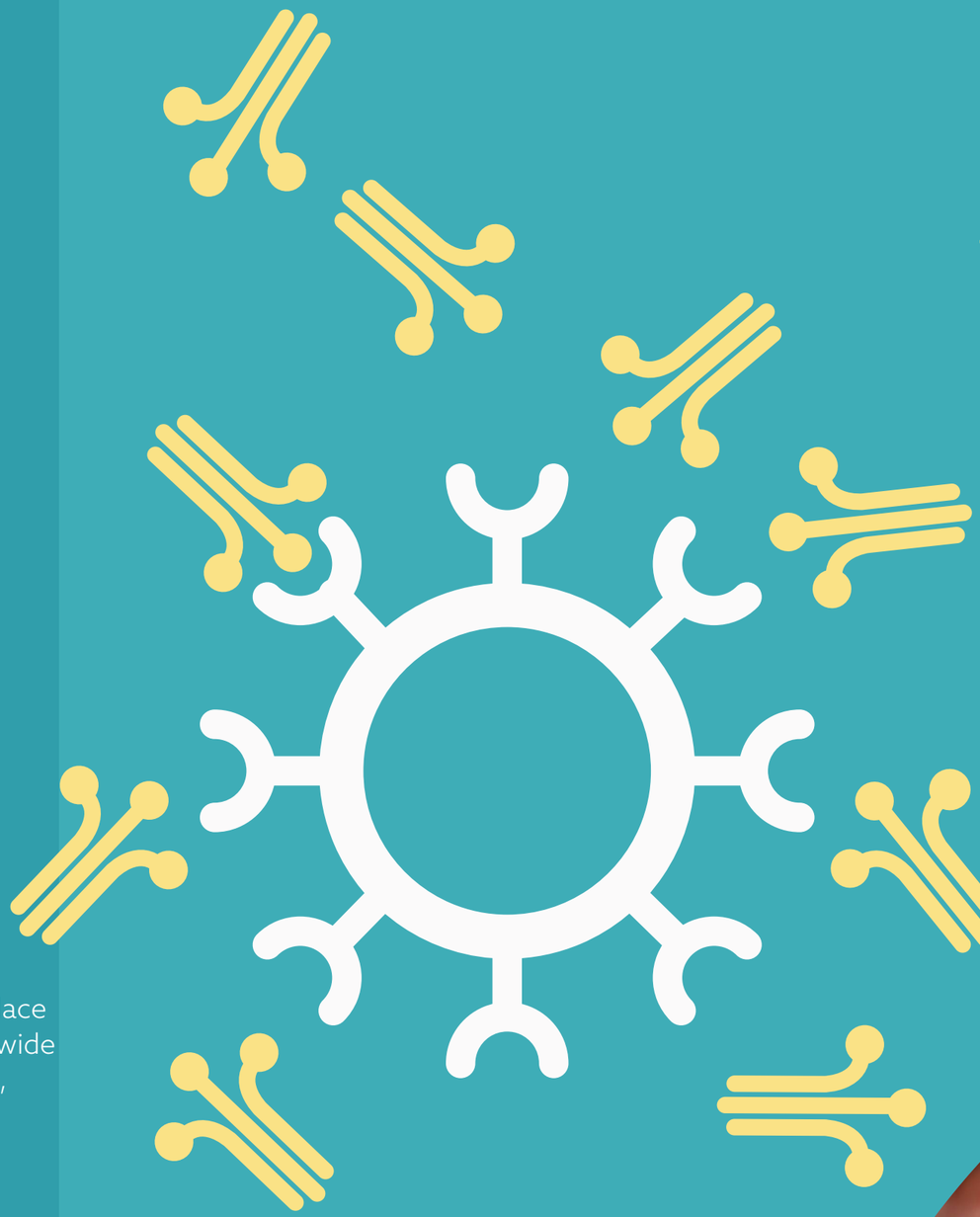
WHAT ARE BIOLOGICS?

[1] **Biopharmaceuticals are among the most sophisticated and elegant achievements of modern science.**

Rather than the small chemical molecule typically manufactured by chemical synthesis, these large complex structures are manufactured within genetically modified living cells. Each of the steps in the manufacturing process are complex and most often specific to the particular drug being manufactured, requiring sophisticated manufacturing processes, expertise and significant financial investment to ensure that any alterations do not have a negative impact on the efficacy of the drug resulting in an unwanted immune response in the patient.

MARKET GROWTH

[2] Biologics currently account for between 17-20% of the pharmaceutical market, worth nearly $200bn and they may replace 70% of chemical drugs within the next two decades. The worldwide pipeline includes more than 450 Biosimilars and 400 Biobetters, nearly all recombinant proteins or monoclonal antibodies in development now.[3]



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TRANSFORMING HEALTHCARE

21st century developments in biopharmaceuticals have provided the pharmaceutical industry with the tools to not just treat disease symptoms, but understand the disease pathway. This has resulted in the development of innovative drugs for the treatment of previously untreatable conditions such as cancer, rheumatoid arthritis, diabetes and multiple sclerosis, ultimately changing the lives of patients with these serious conditions.

[1] McKinsey & Co, Rapid growth in biopharma: Challenges and opportunities, Dec 2014.
[2] Manufacturing Chemist, Global Biosimilars Market, July 2015.
[3] The Biosimilars Information Resource of the Biopharmaceutical Industry. Biotechnology Information Institute. www.biosimilars.com.

MARKET PRESSURES

The ADVANTAGES OF BIOLOGICS over their small molecule predecessors are not without their costs however. Their SAFETY AND EFFICACY, coupled with their SUCCESS IN TREATING patients living with serious illness, empowers Pharma companies to command HIGH PRICES, on average 22 times that of small molecules.[4]

THE HEALTHCARE INDUSTRY

With the healthcare industry coming under increasing pressure to reduce costs and keep within tight budgets, physicians are finding it ever more difficult to account for the **large cost** of biologic products for their patients, with Pharma companies struggling to justify the high prices for any but the most novel drugs.

[4] So AD, Katz SL. Biologics boondoggle. The New York Times, March 7, 2010.
[5] Accelerating Clinical Trials: Budgets, Patient Recruitment and Productivity. Cutting Edge Information.

THE ROLE OF BIOSIMILARS

As with any industry, these pressures will lead to an inevitable change of focus – in this case the growth of Biosimilars. Patent expiries of an increasing number of biologic medicines are fuelling this growth, with the race to market intensified due to a pronounced first-mover advantage with Biosimilars. The delay in getting a drug to market equates to anywhere from $600,000 to $8 million a day in lost revenue.[5]

WHAT IS A BIOSIMILAR?

Unlike a Generic small molecule drug, which has an identical chemical structure to its branded counterpart, a Biosimilar is only required to be similar, not identical, differing in structural features such as the chemical group attached to the protein, while retaining the same protein as the branded reference biologic.

Due to the manufacturing process of a Biologic, within unique biological systems, it is impossible to recreate the manufacturing process exactly when it comes to producing a Biosimilar. Each manufacturing process is unique to each manufacturer, thus creating distinct differences between Biosimilars and the branded biologic counterpart.

GENERICS VS BIOSIMILARS

Similar to small molecule Generics, a Biosimilar costs less than its branded counterpart. However high R&D costs, including the costs of comparator Biologics, as well as fierce competition from other Biosimilar manufacturers, negatively impact the potential cost difference available. Smooth running of and tight control of the supply chain are crucial to ensuring that these high R&D costs are kept to a minimum, ensuring the best return of investment.

THE CHALLENGES FOR BIOLOGICAL PRODUCTS

COST AND TIME

With the pressures of delivering new products into market, delays in approvals can equate to between $1m and $8m per day of lost revenue. The **average cost per patient** for a typical Phase III trial has **almost doubled** in the past 5 years.

Coupled with reducing revenues of existing molecules, the pressure to attain **first-mover advantage** is huge. This is intensified for the growing Biosimilars segment where getting to market first is everything.

COST AND TIME

GLOBALISATION

LACK OF STABILITY DATA

REDUCED INVENTORY

VARIABILITY IN PATIENT ENROLMENT

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WANT MORE DETAIL?

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OUR SOLUTIONS IN ACTION

HAVE YOU CONSIDERED?

Due to the complexity of the Biologics industry, including the many challenges that will be faced, it is critical to your drug development success to consider the following:

BLINDING OF VIALS AND SYRINGES

USING AUTOMATION

ROLL OVER TO FIND OUT MORE

LABEL DESIGN

REFRIGERATED PACKAGING

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BLINDING OF VIALS AND SYRINGES

Biological investigational products now come in many different delivery formats – such as vials for injection, auto-injector pens and IV bags for infusion. These can be challenging to blind due to basic differences in size, shape, colour and components used. Also techniques such as component replacement (plunger rods, finger flangers) from prefilled syringes can be replaced with a different colour or type, so that the supplies are blinded.

- Removal of commercial labels from the prefilled syringe prior to application of clinical label.
- Blinding at outer carton level, to facilitate unblinded staff at site dispensing/making up patient doses.

Consideration can be given to double dummy clinical study design.

Please refer to our **previous eBook on Blinding.**

OUR SOLUTIONS IN ACTION

ADDITIONAL CONSIDERATIONS

FOR CLINICAL SUPPLY PACKAGING OF BIOLOGICS:

THE NEED FOR GLOBAL PACKAGING HUBS

There are three impacting factors to construct the optimum clinical supply chain in terms of geography:

1. Where are the bulk / clinical batches of biological material being produced?

2. What are the options for clinical packaging sites?

3. What are the trial destinations?

These questions require the sponsor and partner company to establish a best fit scenario for their clinical supply chain. It is important therefore to have clinical packaging hubs and depots to cater for the global nature of biological development and sponsor goals.

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THE NEED FOR GLOBAL PACKAGING HUBS

POOLING SUPPLIES & JUST IN TIME LABELLING

SUPPLY CHAIN MANAGEMENT

OUR SOLUTIONS IN ACTION

ALMAC AND PACKAGING OF BIOLOGICAL CLINICAL SUPPLIES

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- Global footprint for packaging of Biological products – including huge capacity for +2-8°C labelling rooms
- Cold chain expertise , governance and processes
- Effective deployment of automation for packaging
- Advanced label technology and solutions for challenging Biological products
- End to end temperature surveillance – assurance of quality and delivery for expensive Biologics
- Analytical services and QP release of supplies
- Ability to link data and technology – linking patient activity to the clinical supply chain / packaging

ALMAC CLINICAL SERVICES
Don't forget, we also have huge capacity for solid dose, blinding, packaging and labelling of Clinical Trial Supplies

Almac Clinical Services
Understanding and **Delivering** your Global Clinical Supply Chain

THE CLINICAL SUPPLY
KNOWLEDGE SHARE SERIES

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COMING SOON

COMING SOON

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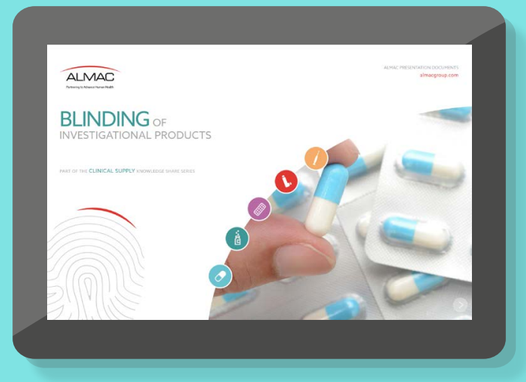
DOWNLOAD OUR **'BLINDING OF INVESTIGATIONAL PRODUCTS'** eBOOK



THIS eBOOK TAKES AN IN-DEPTH LOOK AT:

- The Product Landscape
- Common Trial Types
- Blinding Methods and Techniques
- Consideration Checklists

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