

Coveralls and gloves engineered for **Protection, Compliance and Comfort**



What are biopharmaceuticals?

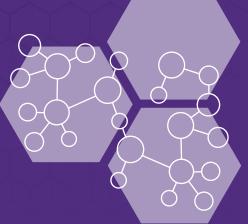
> Complex medicines made from living cells or organisms



Often produced using cutting-edge biotechnological methods



Tend to be heat sensitive, easy to contaminate





Difficult and expensive to make, store and transport



Usually injected into the body



Potential for precise, targeted treatments

What are some of the different types of biopharmaceuticals?

Cytokines

(impacts the interactions and communications between cells)



Monoclonal antibodies

(fights disease like natural antibodies)



Enzymes

(speeds up biochemical reactions)



Immunomodulators

(affects immune response)

Two classes of biopharmaceuticals:



Innovator biologics

An innovator biologic is the original version of biopharmaceutical treatment. It is approved based on, amongst other things, a full complement of safety and effectiveness data.



Biosimilars

A biosimilar is a biopharmaceutical that is highly similar to a specific innovator biologic. It has no clinically-meaningful differences in terms of safety, purity and potency.

Biologics in numbers



insulin is the first biologic cleared for human use



26%

a quarter of US national prescription spending goes to biologics.



of all biologics are sold in the US, the world's biggest market

Biosimilars in numbers



hormone)

the first biosimilar is approved in Europe (a human growth

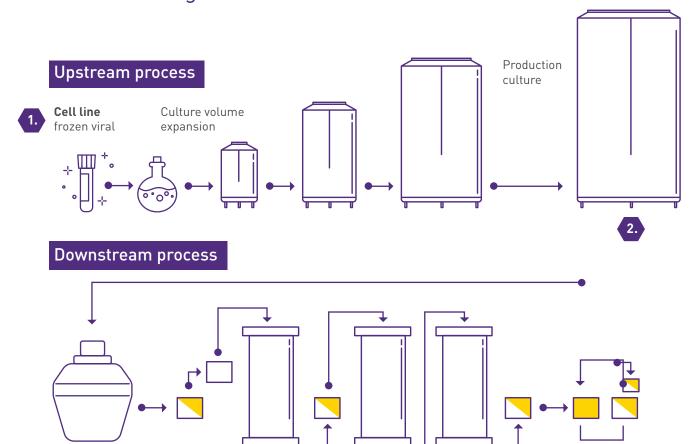


of all biosimilars are sold in Europe

30%

average price difference between a biosimilar and a biologic

Biopharmaceuticals Production at a glance



Virus filtration

Concentration

and formulation



Purpose: choosing the host cell and getting the gene of interest into cells. Product impact: mutation of the gene of interest, host cell differences in protein expression and post-translational modifications, host cell impurities, level of protein expression

Chromatographic

purification

Cell culture:

Centrifugation/ depth filtration

Purpose: production of the target protein under target growth conditions (temperature, media, pH, etc.)

Product impact: process productivity, post-translational modification, product degradation and host cell impurity levels

Purification:

Purpose: removal of host cell and impurities through centrifugation, filtration and chromatography using target conditions (temperature, pH, flow rates, and binding density, etc)

Product impact: extent of removal of impurities or product modifications (wanted or unwanted), protein degradation/ aggregation, biological activity.

Formulation:

Purpose: final concentration and placing the protein in target buffer and container for long-term storage and shipment.

Product impact: formulation of aggregates/ product degradation, impurities that can cause immune reactions, shelf life

Transitioning from Upstream to Downstream

UPSTREAM

Cell Bank Vial

Cell Culture Scale-Up

Production Bioreactor

Cell Separation

Clarified Harvest

Kimtech™ A8 & A7P+ A flexible solution for Upstream and Downstream operations











Kimtech™ Polaris™ Xtra™ Nitrile Gloves

- ➤ Kimtech™ Gloves
- ➤ Kimtech™ Face Masks
- Ximtech™ A7P+
- ➤ Kimtech™ A8 Apparel

DOWNSTREAM

Primary Purification

Viral inactivation

Secondary Purification

Viral Filtration

Pre-formulation

Drug Substance



- **>** Kimtech[™] Gloves
- ➤ Kimtech™ Face Masks
- ➤ Kimtech™ A8 Apparel
- ➤ Kimtech™ A8 Unitrax Shoecovers



Kimtech™ Polaris™ Xtra™ Nitrile Gloves



Kimtech™ Purple Nitrile™ Xtra™ Gloves



Kimtech™ G3 White Nitrile Gloves



Kimtech™ G3 NxT™ Nitrile Gloves





Downstream Critical Operations



Kimtech™: A flexible Head To Toe Solution for aseptic fill finish operations. Compatible with industry preferred VHP decontamination process





Kimtech™ G3 Sterile White Nitrile Gloves



Kimtech[™] G3 Sterile Sterling[™] Nitrile Gloves



Kimtech™ G3 Sterile Latex Gloves



Kimtech™ Sterile iHAM Kimtech™ Sterile Hood Kimtech™ Sterile Face Masks



Kimtech™ Sterile Apparel



Kimtech™ Sterile Boot Cover

Risk for process and product

- > Particles Contamination
- > Bio-contamination
- Molecular contamination

Risk for personnel

- Sanitizers
- Disinfectants
- > Chemical & cytotoxic

V

Risk of Sterility Assurance

High vacuum package system that guarantee sterility (SAL 10-6) at the point of use



Risk of Contamination during donning

Package folded system that reduce contamination risk during aseptic gowning, making aseptic gowning easier and less time consuming.



Risk of Contamination in operations

Quality by design

- Materials that reduce contamination (Helmke Drum Test Cat 1) and assure optimal PFE and BFE (95% consistently).
- Design that improves fit and comfort in aseptic operations to maintain ideal body conditions and reduce risk of CFU.
- Design that eliminates gaps and reduce risk of particle and bacteria contamination from the operator.

Important Considerations

What was good enough in the past will not be in the future - single use is now a trend

Kimtech™ single use solutions makes your customer compliant at all levels from Global compliance to higher operator satisfaction & effectiveness

Financial benefits

- Cost impact per entry only when in use
- Cost impact on production only when the product is needed (holiday, sick leave = NO COST)
- No hidden costs and added flexibility
- Globally available
- > Validation and audit results are shareable
- Qualification and Implementation support via APEX
- Working capital optimization through distributors

Operations benefits

- > Eliminate the risk for cross contamination
- PFE and BFE performances are consistent in use
- > Reduce and manage the Risk for Sterility assurance
- Reduce and manage the risk for operator errors during aseptic donning
- Reduce and manage the risk for airborne and microbiological contamination during operations
- Address both risk for process, product and people
- Packaging is compatible with latest VHP decontamination processes
- Packaging in multiple of 25 is friendly for small and bigger size changing rooms ideal for the smallest number of entries and allow for scale up
- Distributor Partner can implement various solutions to guarantee availability and safety stocks
- RightCycle™ Programme available in selected countries

RightCycle[™] Programme

We are committed to reducing environmental impact at every stage in a product's life cycle. With the RightCycle™ Programme previously hard-to-recycle products like nitrile gloves and cleanroom garments are turned into a variety of useful, eco-friendly products. (Available in the UK, Ireland, France, Spain, Germany, Austria, Belgium, the Netherlands and Switzerland)





Apex[™] Programme

Change can be disruptive, especially in environments where personal safety and contamination control are essential. That's why we developed The Apex™ Programme, a consultative approach that ensures a seamless transition to the Kimtech™ Brand of products.

Assessment

Understand your company, operating environment and challenges

Preparation

Connect with the right stakeholders, develop a collaborative approach, determine what success looks like

Implementation

Actively train employees, ensure they own and embrace the change

Results

Ensure the change is properly understood, achieve your stated goals, post satisfaction survey



	Product Code	Size / Format	Total Case content	Material	Characteristics	ISO or Class	Regulatory	Chemical Splash Protection	Micro- organisms Protection	Recyclable ⁸
Sterile Cleanroom	Range									
Kimtech™ Sterile Clea	nroom Glov	/es								
G3 Sterile Sterling™ Nitrile Gloves	11821 to 11828	6.0 to 10.0	300 pairs	Nitrile	slick - double donning	ISO 5 Class A/B	PPE Cat III	EN ISO 374-1 Type C	EN ISO 374-5 Virus	③
G3 Sterile White Nitrile Gloves	56887 to 56894	6.0 to 10.0	200 pairs	Nitrile	slick - double donning	ISO 5 Class A/B	PPE Cat III	EN ISO 374-1 Type B (KPT)	EN ISO 374-5 Virus	(3)
G3 Sterile Latex Gloves	56842 to 56849	6.0 to 10.0	200 pairs	Latex	slick - double donning	ISO 5 Class A/B	PPE Cat III	EN ISO 374-1 Type C	EN ISO 374-5 Virus	,
Kimtech™ Sterile Clea	nroom App	arel								
A5 Sterile Cleanroom Coverall	88800 to 88806	S to 4XL	25 garments	SMS	vacuum packed	ISO 5 Class A/B	PPE Cat III	Type 5 Type 6		②
A5 Sterile Cleanroom Hood with ties	25797	Universal	100 hoods	SMS	vacuum packed	ISO 5 Class A/B	PPE Cat III	Type 6 (PB)		∅
A5 Sterile Cleanroom Hood & Mask	36072	Universal	75 hoods	SMS	vacuum packed	ISO 5 Class A/B	PPE Cat III	Type 6 (PB)		(3)
A5 Sterile Overboots with vinyl sole	12922 / 88808	S/M and univ.	100 pairs	SMS	vacuum packed	ISO 5 Class A/B	PPE Cat I			
A5 Sterile Overboots with wrap-around vinyl foot	31683 / 31696	S/M and univ.	100 pairs	SMS	vacuum packed	ISO 5 Class A/B	PPE Cat I			
A5 Sterile sleeves	36077	Length 45 cm	100 pairs	SMS	vacuum packed	ISO 5 Class A/B	PPE Cat I			∅
Kimtech™ Sterile Face	Masks									
M3 Sterile Pouch-Style Face Mask	62483	Width 25 cm	200 masks	PE ⁽¹⁾ /[PE/ PET] ⁽²⁾ /PP ⁽³⁾	with headbands	ISO 5 Class A/B				
M3 Sterile Pleat-Style Face Mask	62467	Width 18 cm	200 masks	PE ⁽¹⁾ /[PE/ PET] ⁽²⁾ /PP ⁽³⁾	with ties	ISO 5 Class A/B				
M3 Sterile Pleat-Style Face Mask	62470	Width 18 cm	200 masks	PE ⁽¹⁾ /[PE/ PET] ⁽²⁾ /PP ⁽³⁾	with earloops	ISO 5 Class A/B				
M3 Sterile Pleat-Style Face Mask	62494	Width 23 cm	200 masks	PE ⁽¹⁾ /[PE/ PET] ⁽²⁾ /PP ⁽³⁾	with ties	ISO 5 Class A/B				
Non-Sterile Cleanro	oom Range	e								
Kimtech™ Cleanroom	Gloves		1							•
G3 White Nitrile Gloves	56880 to 56886	XS to XL	1000 gloves	Nitrile	tacky	ISO 3 or higher Class C/D	PPE Cat III	EN ISO 374-1 Type B (KPT)	EN ISO 374-5 Virus	∅
G3 NxT™ Nitrile Gloves	62990 to 62995	XS to XL	1000 gloves	Nitrile	slick - double donning	ISO 3 or higher Class C/D	PPE Cat III	EN ISO 374-1 Type B (KPT)	EN ISO 374-5 Virus	(3)
Kimtech™ Apparel										
A8 Particles Protection Coverall	47691 to 47697	S to 4XL	25 garments	SMS ^[4]	individually packed	ISO 6 or higher Class C/D	PPE Cat III	Type 5 Type 6		(3)
A8 overshoes	39370 to 39372	S / Univ/ XL	300 overshoes	SMS ^[4]	fully coated	ISO 6 or higher Class C/D	PPE Cat I			
A7P+ Lab Coat	97700 to 97740	S to 2XL	15 lab coat	Laminated SMS ⁽⁴⁾	individually packed	ISO 8 or higher	PPE Cat III	Type 6 (PB)	EN 14126:2003	(3)
Kimtech™ Cleanroom	Face Masks	5						KX		
M3 Pleated-Style Face Mask	62451	Width 23 cm	500 masks	PE ⁽¹⁾ /[PE/ PET] ⁽²⁾ /PP ⁽³⁾	with earloops	ISO 3 or higher Class C/D				
M3 Pleated-Style Face Mask	62465	Width 18 cm	500 masks	PE ⁽¹⁾ /[PE/ PET] ⁽²⁾ /PP ⁽³⁾	with earloops	ISO 3 or higher Class C/D				
Laboratory Range				TAT						
Kimtech™ Laboratory	Gloves			T T					人人	人
Polaris™ Nitrile Gloves	62000 to 62004	XS to XL	10 x 100 ⁽⁵⁾ gloves	Nitrile	textured fingertips	ISO 6 or higher Class C/D	PPE Cat III	EN ISO 374-1 Type B (JKOPT)	EN ISO 374-5 Virus	(3)
Polaris™ Xtra Nitrile Gloves	62100 to 62104	XS to XL	10 x 50 gloves	Nitrile	textured fingertips	ISO 6 or higher Class C/D	PPE Cat III	EN ISO 374-1 Type B (JKOPT)	EN ISO 374-5 Virus	(3)
Purple™ Nitrile Gloves	90625 to 90629	XS to XL	10 x 100 ⁽⁵⁾ gloves	Nitrile	textured fingertips	ISO 6 or higher Class C/D	PPE Cat III	EN ISO 374-1 Type B (JKT)	EN ISO 374-5 Virus	(0)
Purple™ Xtra™ Nitrile Gloves	97610 to 97614	XS to XL	10 x 50 gloves	Nitrile	textured fingertips	ISO 6 or higher Class C/D	PPE Cat III	EN ISO 374-1 Type B (JKT)	EN ISO 374-5 Virus	(1)
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^{*} For more details on the products please refer to the corresponding technical data sheet

^[1] PE: polyethylene

^[2] PE/PET: polyethylene/ polyethylene terephtalate

^[3] PP :polypropylene

^[4] SMS : spunbond - meltblown- spunbond

⁽⁵⁾ 10 x 90 for size XL

⁽⁶⁾ 10 x 140 for size XL

^[7] 10 x 170 for size XL

IB If non-hazardous, this product can be recycled through The RightCycle Programme by Kimberly-Clark Professional™, an innovative recycling programme that diverts non-hazardous Kimtech™ branded nitrile gloves and coveralls from landfill. The programme is available in the UK, Ireland, France, Spain, Germany, Austria, Belgium, Netherlands and Switzerland.



Our website offers additional resources to help you select the right product for the right application. It also offers a rich source of data for your business, visit www.kimtech.eu for:

- Download glove chemical permeation data: from the top menu select "Resources" and then "Chemical Permeation"
- Certificate of Analysis and Certificate of Irradiation: from the top menu select "Resources"
 and then "Certificate"



For any other questions and technical assistance contact us at kimtech.support@kcc.com

www.kimtech.eu

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