

KIMTECH™

Solutions for the Biotech industry

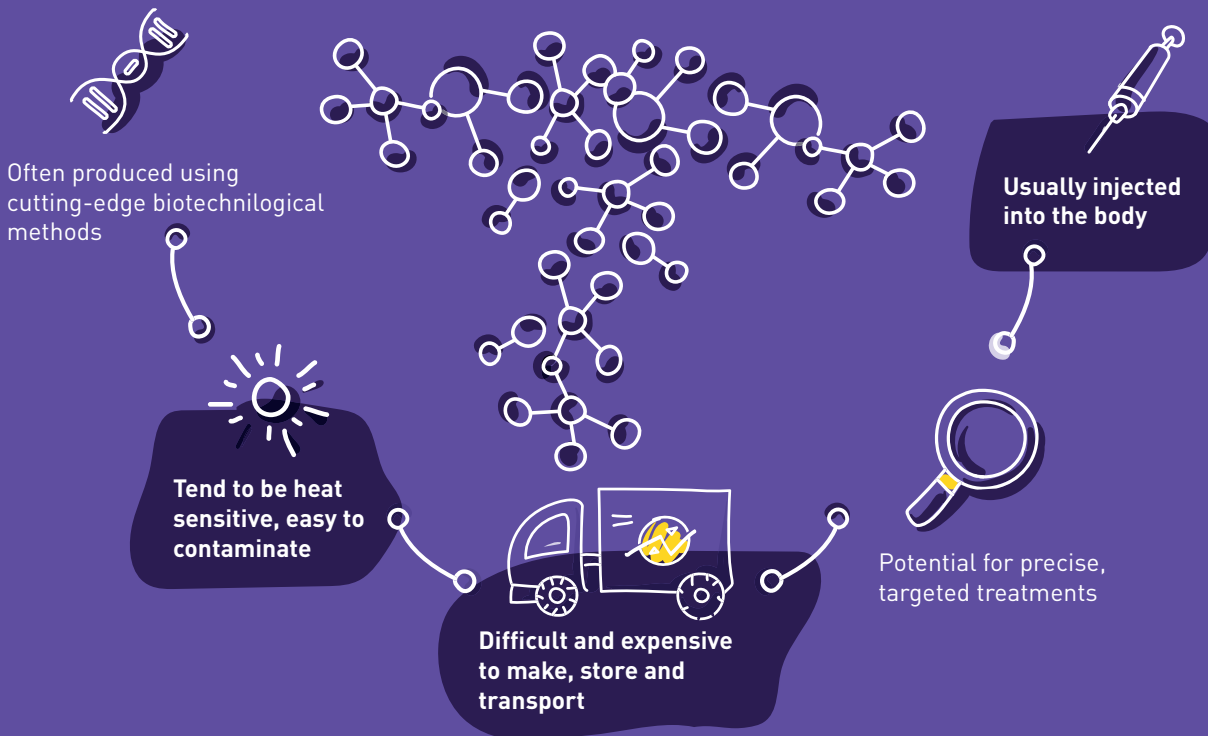
Coveralls and gloves engineered for
Protection, Compliance and Comfort



 **Kimberly-Clark**
PROFESSIONAL

What are biopharmaceuticals?


› Complex medicines made from living cells or organisms




What are some of the different types of biopharmaceuticals?

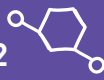
- ⬡ **Cytokines**
(impacts the interactions and communications between cells)
- ⬡ **Monoclonal antibodies**
(fights disease like natural antibodies)
- ⬡ **Enzymes**
(speeds up biochemical reactions)
- ⬡ **Immunomodulators**
(affects immune response)


Two classes of biopharmaceuticals:

 **Innovator biologics**
An innovator biologic is the original version of biopharmaceutical treatment. It is approved based on, among 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

1982 
insulin is the first biologic cleared for human use


26% 
a quarter of US national prescription spending goes to biologics.

59% 
of all biologics are sold in the US, the world's biggest market

Biosimilars in numbers

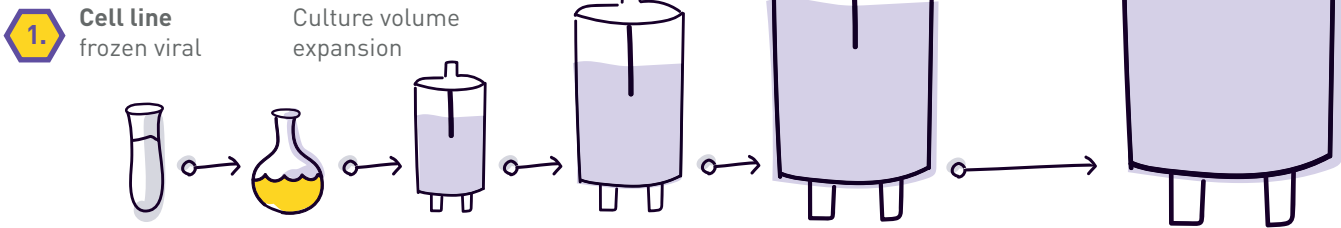
2006 
the first biosimilar is approved in Europe (a human growth hormone)

87% 
of all biosimilars are sold in Europe

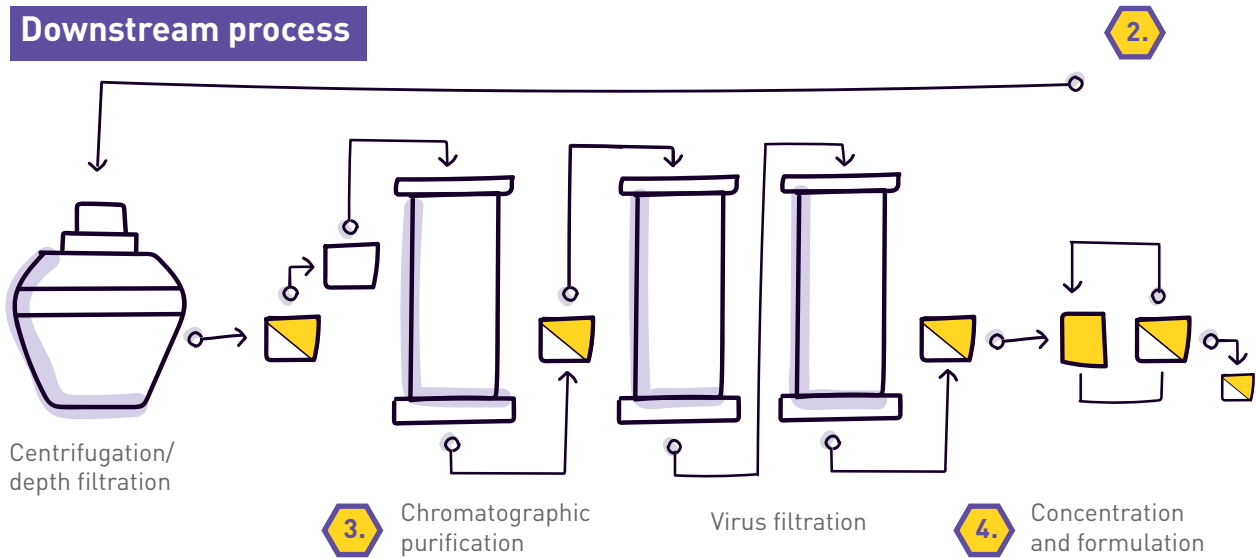
30% 
average price difference between a biosimilar and a biologic

Biopharmaceuticals Production at a glance

Upstream process



Downstream process



1.

Host cell line production:

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

2.

Cell culture:

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

3.

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.

4.

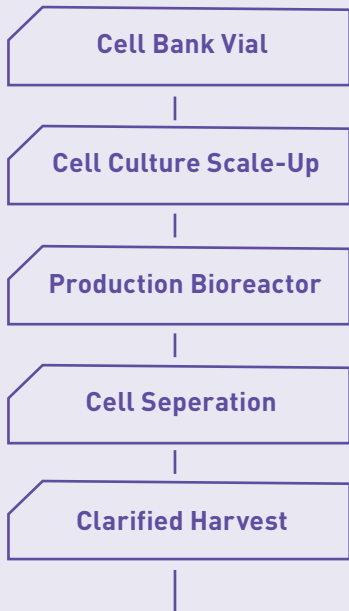
Formulation:

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



Kimtech™ A8 & A7P+

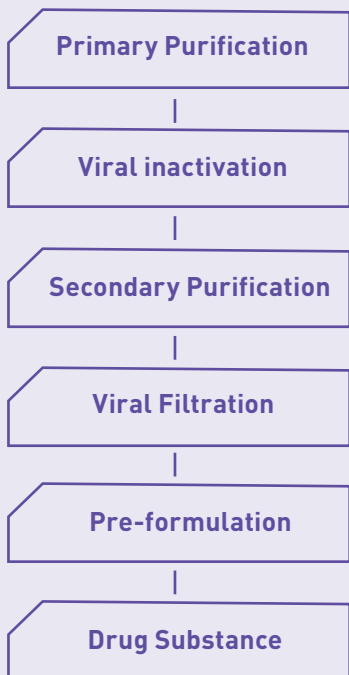
A flexible solution for Upstream and Downstream operations



Kimtech™ Purple Nitrile™ Xtra™ Gloves

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

DOWNSTREAM



- Kimtech™ Gloves
- Kimtech™ Face Masks
- Kimtech™ A8 Apparel
- Kimtech™ A8 Unitrax Shoecovers



Kimtech™ Purple Nitrile™ Xtra™ Gloves



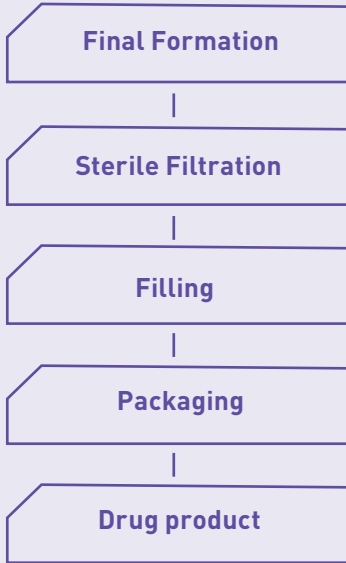
Kimtech™ G3 White Nitrile Gloves



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



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 improve 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 solution 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
- Right Cycle 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 UK, Ireland, Germany, Austria, Belgium and Spain)



APEX

APEX is our proven change management programme, engaging all stake holders to ensure a successful conversion to KCP products.

A - Assess

Understand your company, operating environment and challenges

P - Partner

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

E - Engage

Actively train employees, ensure they own and embrace the change

X - Execute

Ensure the change is properly understood, achieve your started goals

	Product Code	Size /Format	Total Case content	Material	Characteristics	ISO or Class	Regulatory	Chemical Splash Protection	Micro-organisms Protection
Sterile Cleanroom Range									
Kimtech™ Sterile Cleanroom Gloves									
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 (K)	EN ISO 374-5 Virus
G3 Sterile White Nitrile Gloves	HC61160 to HC61110	6.0 to 10.0	200 pairs	Nitrile	slick - double donning	ISO 5 Class A/B	PPE Cat III	EN ISO 374-1 Type C (K)	EN ISO 374-5 Virus
G3 Sterile Latex Gloves	HC1360S to HC1310S	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 (K)	EN ISO 374-5 Virus
Kimtech™ Sterile Cleanroom Apparel									
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	
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)	
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 Certified 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 Certified 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 Certified 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 Certified 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 Cleanroom Range									
Kimtech™ Cleanroom Gloves									
G3 White Nitrile Gloves	HC61010 to HC61014	XS to XL	1000 gloves	Nitrile	tacky	ISO 3 or higher Class C/D	PPE Cat III	EN ISO 374-1 Type C (K)	EN ISO 374-5 Virus
G3 Nx™ 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 C (K)	EN ISO 374-5 Virus
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	
A8 overshoes	39370 to 39372	S / Univ/ XL	300 overshoes	SMS ⁽⁴⁾	fully coated	ISO 6 or higher Class C/D	PPE Cat I		
Kimtech™ Cleanroom Face Masks									
M3 Certified 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 Certified 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									
Kimtech™ Laboratory Gloves									
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
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⁾ PE: polyethylene

⁽²⁾ PE/PET: polyethylene/ polyethylene terephthalate

⁽³⁾ PP :polypropylene

⁽⁴⁾ SMS : spunbond - meltblown- spunbond

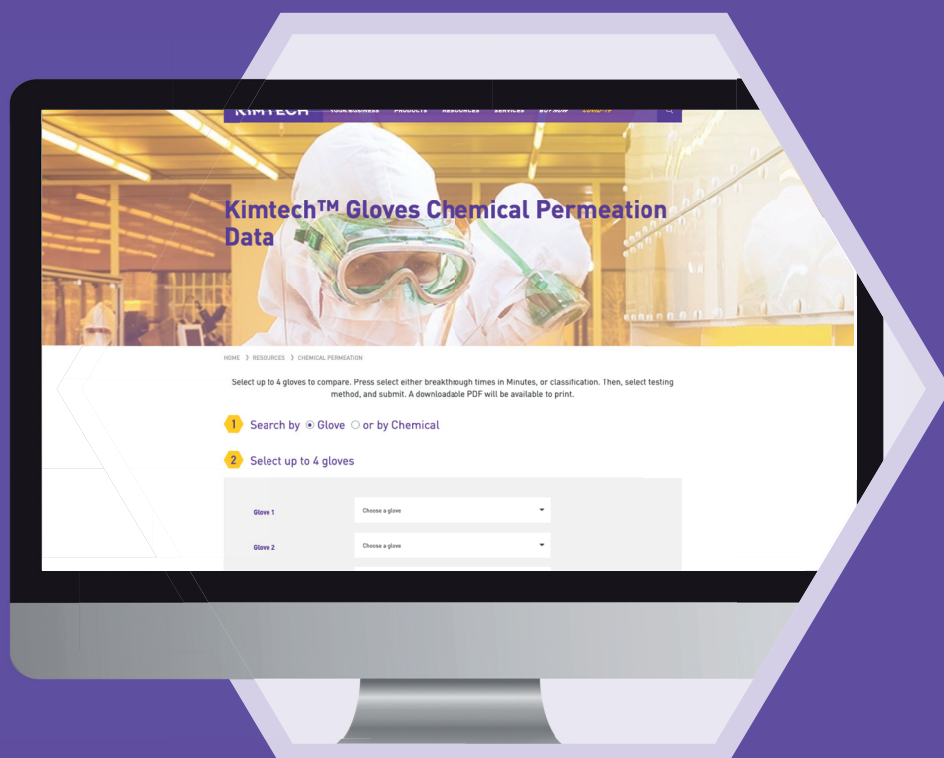
⁽⁵⁾ 10 x 90 for size XL



Chemical Permeation Data

- Visit www.kimtech.eu, from the top menu select resources and then chemical permeation
- Select up to 4 gloves to compare or select a specific chemical. Select either breakthrough times in minutes, or classification.

Chemical	Concentration	Glove Model	IMMEDIATE BREAKTHROUGH TIMES		MINUTE BREAKTHROUGH TIMES		CLASSIFICATION	
			MINUTES	PERCENTAGE	MINUTES	PERCENTAGE	CLASSIFICATION	CLASSIFICATION
Acetic Acid	1%	100-414	1000	100%	1000	100%	100%	100%
Acetone	5%	100-414	1000	100%	1000	100%	100%	100%
Acetone	5%	100-152	1000	100%	1000	100%	100%	100%
Acetone	5%	100-152	1000	100%	1000	100%	100%	100%



- Submit and download your PDF

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