

The Recombumin® product portfolio are the highest quality, animal and human origin-free recombinant human albumins commercially available. Our highly pure, safe and consistent albumins enable you to formulate with confidence.

- The Recombumin® product portfolio are world leading recombinant human albumins (rAlb)
- Albumedix use their 30 years experience with albumin to offer ongoing regulatory and technical guidance to customers globally
- Recombumin is the highest quality animal origin-free rAlb product commercially available
- Produced at ICH Q7 cGMP Quality
- Produced in *Saccharomyces cerevisiae*
- Product form: liquid 50ml vial or 1L BPC (dependent on product)
- Internationally recognized by leading regulatory authorities
- Recombumin is used in the manufacture of approved biopharmaceuticals and medical devices

# Recombumin

Recombinant human albumins



# Recombumin® can address GMP concerns for advanced therapy and biopharmaceutical developers



## Purest albumin available

No mysteries in your process or formulation with unwanted impurities



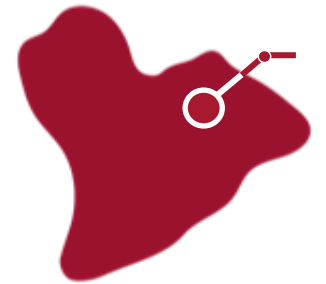
## Proven batch-to-batch consistency

Get a more robust process with the same rHA product received every time



## Human & animal free

Avoid regulatory hurdles with a safe and compliant excipient/stabiliser



## Highest anti-oxidant capacity

Avoiding chemical degradation for increased performance

# Product comparison

Characteristic	Recombumin® Prime	Recombumin® Elite
<b>Recommended application</b>	Drug and Vaccine formulations	Advanced Therapy Medicinal Products
<b>Use in commercialised product</b>	Merck & Co M-M-R® II, ProQuad®	No
<b>USP-NF compliant</b>	Yes	No
<b>Animal-and human-free</b>	Yes	Yes
<b>Purity</b>	≥ 99.0%	≥ 99.0%
<b>GMP</b>	Yes (ICH Q7)	Yes (ICH Q7)
<b>Safety data</b>	Comprehensive non-clinical studies conducted in multiple species (rats, rabbits, guinea pigs, mice) Large PhI safety & tolerability clinical study (i.m. and i.v.) Real world data – extensively used in marketed childhood vaccine	Repeat dose toxicity study in rodents
<b>Regulatory documentation</b>	Open Master File Full master files in US, Canada, Australia, New Zealand and China Full master file to be filed in Japan 2020	Open Master File Full master file in the US Full master file to be filed in Japan 2020
<b>Presentation</b>	50-mL glass vial (20% (w/v), 10 g)	50-mL glass vial (10% (w/v) or 1-L bioprocess container (5 or 100 g)
<b>Production site</b>	Nottingham, UK	Nottingham, UK

