

# Making complex chemical processes commercially viable & regulatorily robust

Client - A global pharmaceutical company engaged in the research, development, and commercialization of dendrimer products for a pharmaceutical, life-science and other applications. Associated with Laurus for the past 12 years

## Program

- A 16kDa polyAA Dendrimer drug candidate approved for primary indication in European Union & a few other countries

## Challenge

- As the size suggests at 16 kDa it's a small molecule that comes with the challenges associated with biopharmaceuticals particularly w.r.t. control of dendrimer fragments
- While there are multiple manufacturers for polyAA SM, none were available for consistent delivery of the RSM viz., polyAA monomer at the requisite quality and regulatory documentation
- The process as such is beset with multiple challenges w.r.t. starting with very low volumes & finishing with very process volumes across 8 stages some of which need to be handled under <30% RH including final isolation & drying

## Solution

- Laurus worked extensively on the chemistry and established controls that enabled consistent & high-quality product. This required introducing new techniques like Ultrafiltration at scale
- Laurus developed a process for manufacture of the PolyAA monomer & scaled it up within its facilities. Similarly derisked other critical RMs by developing local vendors where possible & by qualifying alternate vendors for most
- Re-engineered & dedicated the multi-product suite exclusively for this client & ensured this block/ suite can support Launch & early commercial quantities

## Outcome

- The client launched the product successfully for primary indication in EU & two alternative indications across the world Laurus has been supporting the commercial supplies seamlessly
- Given the scale-capability of Laurus for the API, client could comfortably pursue alternate indications of the product and succeeded to expand the potential of their flag-ship product
- Client chose Laurus as its CDMO for two other advance intermediates (Dendrimer based) of other portfolio programs
- 20 BATCHES TOTALING TO 600KG DELIVERED AS ON DATE