

FUJIFILM

Diosynth
biotechnologies

Partnering
from Gene to
Antibody Drug
Conjugation



Fujifilm Diosynth Biotechnologies and Piramal Healthcare have formed a partnership to provide their customers with **efficient** and **well planned** Antibody Drug Conjugate Development and Manufacturing

- Efficient material supply during critical development stages
- Early joint technical involvement can help reduce risks
- Shared analytical activities to help reduce duplication of efforts
- Simplifies Supply Chain Management



Cell line development

- Vector construction
- Cell line development
 - High throughput screening and selection methodology
 - Apollo™ mammalian expression system utilizing proprietary
 - CHO DG-44 cell lines
 - Construction, cloning and selection
 - Animal component free
- Mammalian cGMP cell bank manufacturing and storage

Cell culture process development

- Standard approach for mAbs with a major focus on single-use technologies for cell culture, harvest and purification
- Micro- and lab-scale bioreactors allow quick process development
 - ambr15, multiple 2L, 5L, 10L, 15L and 200L bioreactor
 - 200L Pilot Scale

cGMP manufacture

Broad range of cGMP production scales at our Billingham UK or Research Triangle Park, NC, USA facilities:

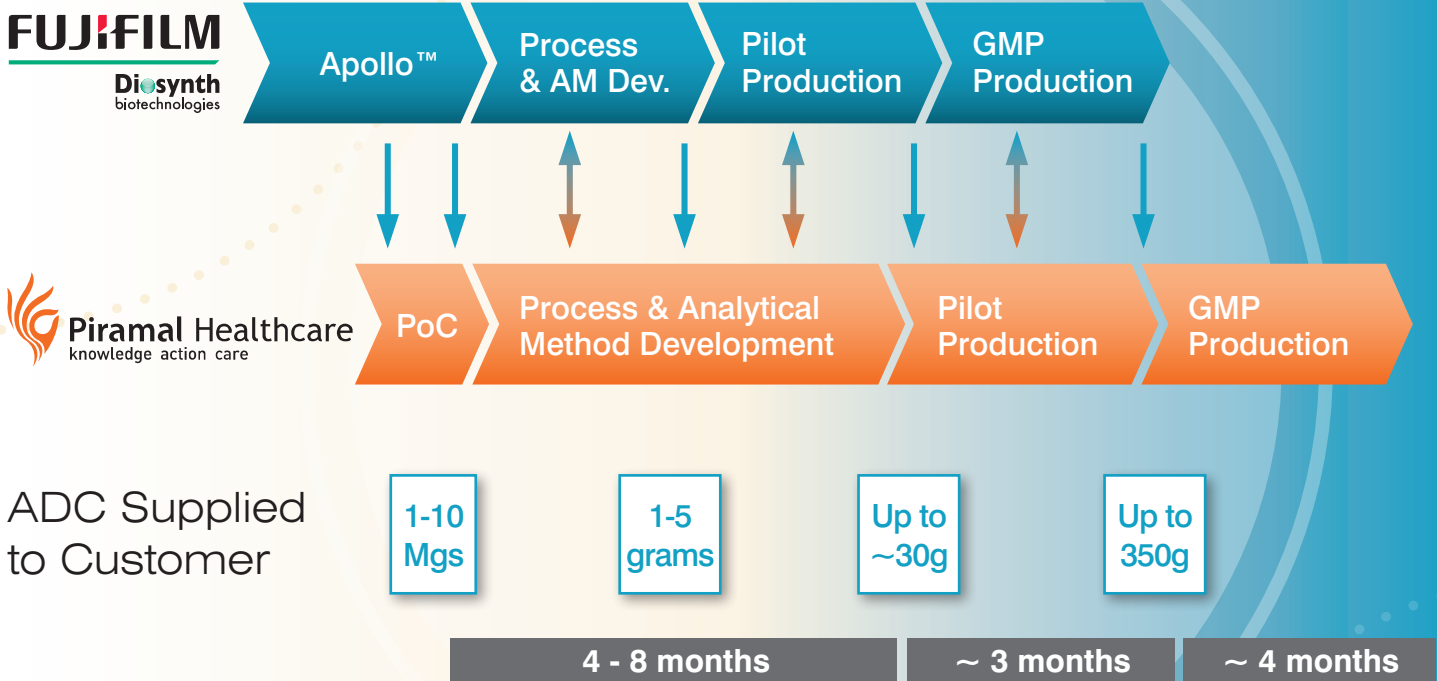
- Stainless Steel: 650L and 2,000L
- Single Use: 200L, 500L, multiple 1,000L, multiple 2,000L

Analytical methods

One phase of analytical method development between Fujifilm and Piramal for your IND, BLA protocol enabling increased efficiency and shorter timelines:

- Product release - SE-UPLC, CEX-UPLC, iCE280, CE-SDS
- Product characterisation - Micro-Flow Imaging™, NP-UPLC Glycan, ESI-MS, DSC, CD
- Process related impurities - DNA, HCP, residual protein A
- Force degradation and impurity characterization

Partnering from Gene to ADC



Partnership Benefits

- Early transfer of material from Fujifilm to Piramal - rapid demonstration of conjugation
- Transfer of analytical methods from Fujifilm to Piramal
- Consistent mAb from Fujifilm = consistent ADC from Piramal
- Integrated program management teams
- ADC development starts with mAb development

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