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SUCCESS STORY

Scaling bispecific antibody process development

From stable pool to GMP-ready supply in 10 months

The Challenge

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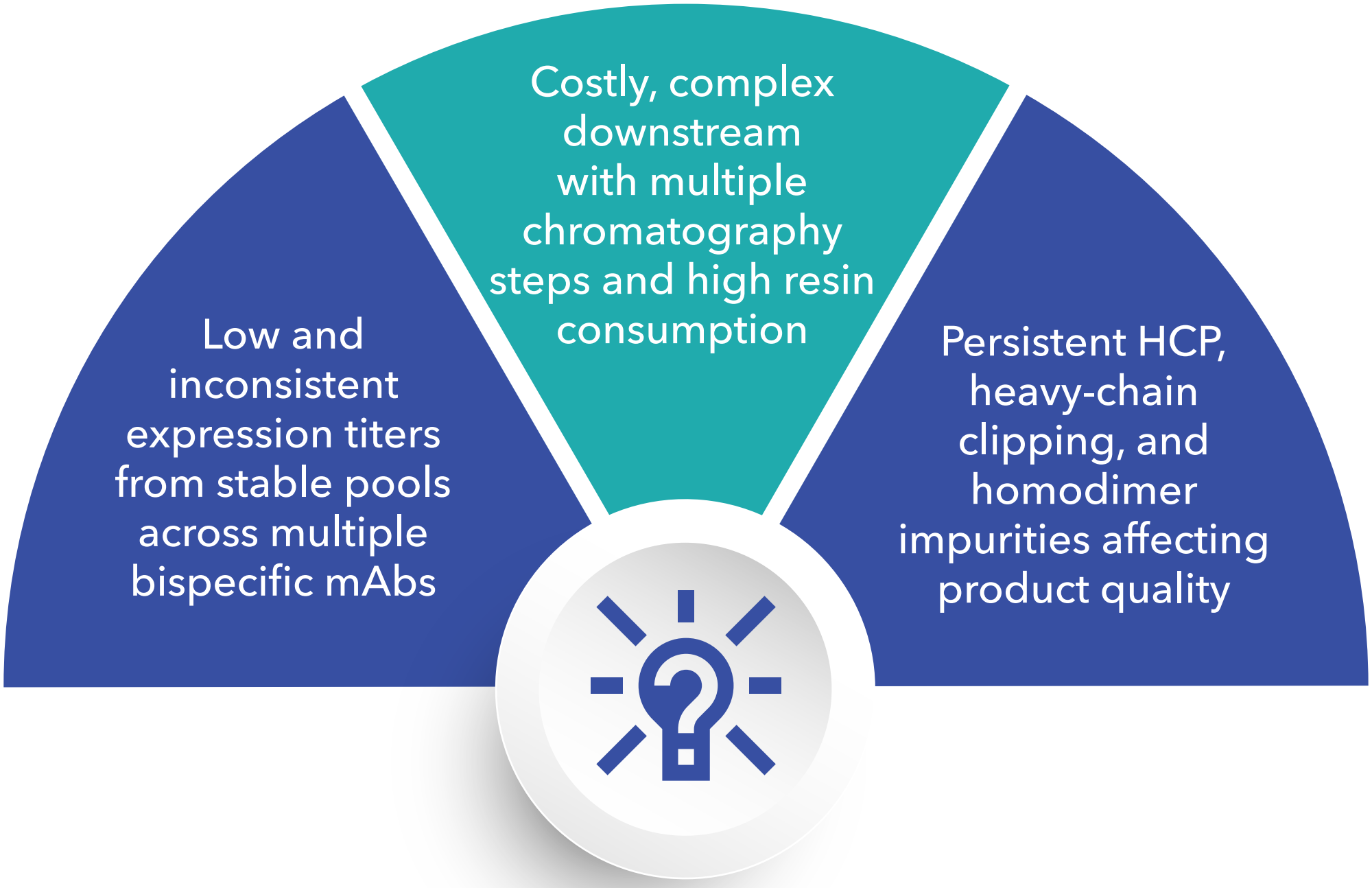

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Our Approach

Deployed an analytics-driven characterization strategy

1 AMBR15 clone screening, media and feed regime optimization with temperature, pH and additive tuning

2 Bioreactor process scale-up across 5L/10L → 200L → 1KL SUB platforms

3 Process simplification - one chromatography step eliminated without compromising quality

- N-1 stage process intensification for high-density seeding into production
- Protein A resin screening and elution optimization using peak-fraction cut-off criteria

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The Impact

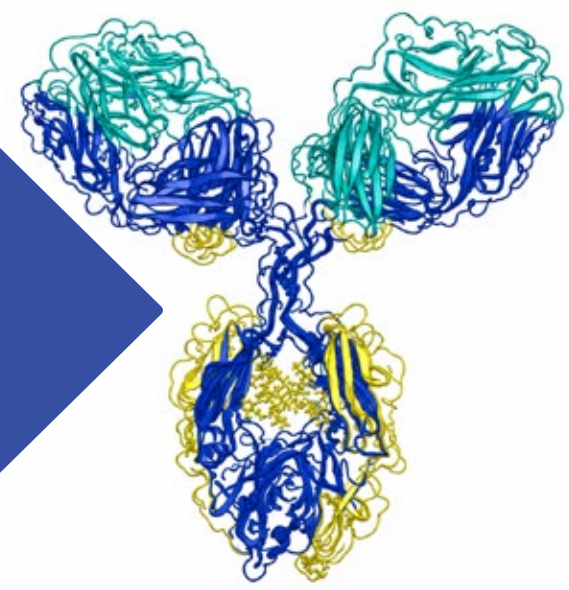
Release-ready analytical package to ensure reliable Product Quality and increased Process Efficiency

Titer ~2× improvement

>99% product purity
at DS stage

Impurity profile controlled
HCP, clipping, homodimer

Resin cost ~halved
2× binding efficiency



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Unlock complex bispecific challenges with confidence

If you're facing hurdles in cell line, upstream, or downstream process development, we'd be happy to explore solutions with you.

Connect with us to discuss your program

Discover how Aurigene can accelerate your development journey