
The Development of a Manufacturing and Preparation Toolbox

The Challenge

Advanced Therapies (AT) have revolutionised the treatment of diseases, particularly those which were previously regarded as intractable to treatment and cure. Although ATs offer great promise, they also present significant challenges, including the exacting requirements of their preparation, manufacture and formulation. These involve a complex series of steps requiring specialist manufacturing techniques and compliance with strict regulations to ensure the quality and safety of the therapeutic. These novel medicines vary in character and each manufacturer completes these steps in slightly different ways.

The Solution

The Manufacturing and Preparation Toolbox produced by the Northern Alliance Advanced Therapies Treatment Centre (NA-ATTC) is addressing these challenges by identifying the areas with high rates of variation across the AT manufacturing sector then developing standardised analytical templates and techniques to ensure quality is maintained. Further to these technical solutions, the toolbox also addresses the stringent pharmaceutical requirements of ATs from a regulatory and NHS perspective.

The results

Through consultation with relevant experts and key stakeholders in the NA-ATTC, and more widely in the UK, a comprehensive toolbox is being assembled. It includes:

- FAQ Tables - detailing regulatory expectations in manufacture
- quality & analytics documents - explaining the reasons for specific requirements in AT manufacturing processes)
- Analytical validation plans - to provide standardisation in cell analysis and preparation techniques across multiple platforms and locations
- Critical evaluations - identifying barriers in current AT manufacture processes

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- Education poster - guidance for researchers and manufacturers detailing good manufacture processes (GMP)
- Detailed flow diagrams - demonstrating the different models used in hospitals for CAR-T delivery
- Documents detailing best practice – in various key areas such as pharmacy and manufacturing techniques
- Detailed reports and guidance documents - for pharmacy departments and manufacturers

Making further impact



This NA-ATTC toolbox will soon be widely available through the ATTC Network website (www.theattnetwork.co.uk), permitting key players in industry and the NHS to streamline the manufacture and preparation of Advanced Therapies. The primary benefit will be the adoption of best practice in the manufacture and preparation of ATs which, in turn, will expedite the pathway towards availability to patients and commercial success.

With thanks to contributing NA-ATTC partners, this work was led by Newcastle University, The Newcastle upon Tyne Hospitals NHS Foundation Trust and The Scottish National Blood Transfusion Service in collaboration with Alcyomics Ltd, Autolus Therapeutics PLC, Miltenyi Biotec, NHS Blood & Transplant, pan-UK Pharmacy Working Group and RoslinCT

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