pharma equipment

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ENGINEERING THE NEXT GENERATION OF ADC MANUFACTURING

Precision. Containment. Process control.

This whitepaper explores the engineering challenges involved in taking antibody-drug conjugate (ADC) manufacturing from laboratory development into robust, repeatable and scalable production. Because ADCs combine sensitive biological materials with highly potent cytotoxic payloads, manufacturers must manage precision, product protection, operator containment and aseptic processing simultaneously.



Author

Dave Seaward, Founding Director at 3P innovation

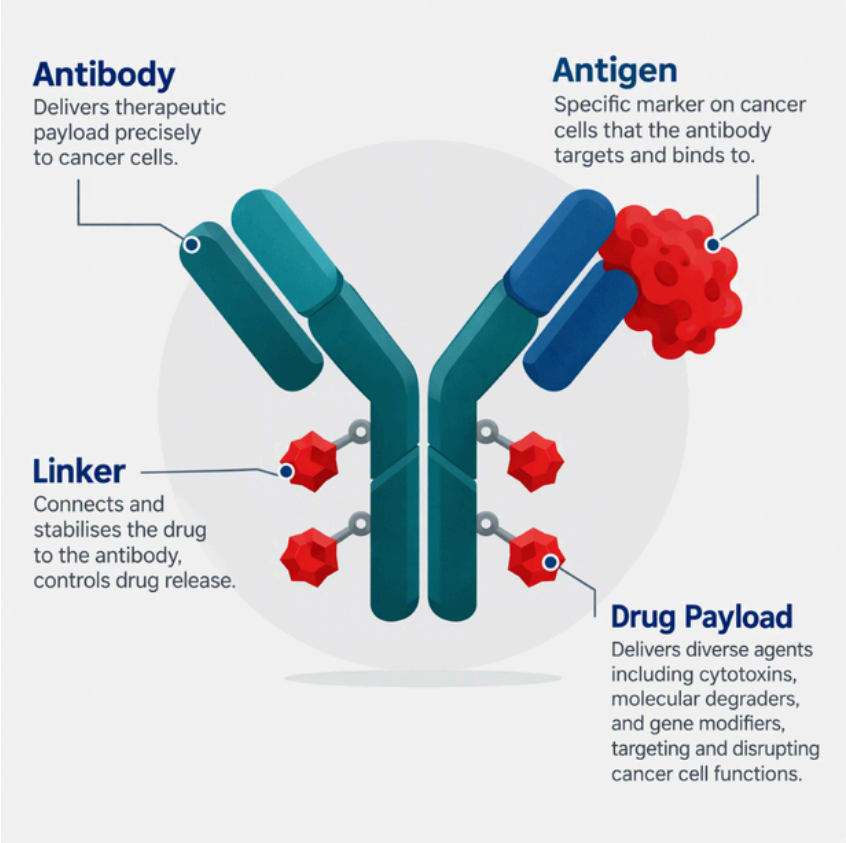
INTRODUCTION

Antibody–drug conjugates (ADCs) combine the targeting capability of monoclonal antibodies with highly potent drug payloads. Their therapeutic promise lies in directing cytotoxic payloads towards tumour cells, with the aim of limiting systemic exposure and off-target toxicity. Manufacturing these complex products brings together a demanding combination of biological processing, precision chemical reactions, potent-compound containment and aseptic pharmaceutical production.

For manufacturers, the challenge is not simply automating an established sequence. It is developing robust and scalable processes that protect product integrity, ensure repeatability and safeguard operators. Addressing these challenges requires precision dispensing, low-shear fluid handling, process control and isolator-based automation- the capabilities that 3P innovation brings together.

The challenge of controlled conjugation

An ADC typically comprises an antibody, a linker and a cytotoxic payload. The drug-to-antibody ratio (DAR), and particularly its distribution, can influence potency, stability, pharmacokinetics and safety. Reagent concentration, addition rate, pH, temperature, mixing and reaction time must therefore be carefully controlled.



Precision liquid dispensing

Controlled linker-payload addition, reaction reagent dispensing, buffer preparation, automated sampling, and final drug-product filling are potential ADC applications for customised precision liquid dispensing systems. At 3P innovation, we develop these systems, some of which offer very low shear. Accuracy depends on the entire fluid path, not just the pump, including tubing, valves, connections, calibration, material compatibility and dispensing geometry.

Precision powder dispensing

Highly potent payloads and some formulation ingredients may arrive as powders. Small quantities can be difficult to dispense accurately, particularly when materials are cohesive, electrostatic or poorly flowing. At 3P innovation, our specialist powder feeding and dosing expertise can support the development of contained, reproducible material handling. Our proprietary Fill2Weight powder dispenser was originally developed to dispense 5–20 mg into dry powder inhalers and has since been applied to multiple sectors, including aseptic powder dispensing. Its ability to dispense continuously at rates as low as 20 mg/min, with a 500:1 turndown ratio, is relevant to the challenge of accurately handling small quantities.

ENGINEERING PRINCIPLE

Precision is a property of the complete process, not simply the dispensing device



PROTECTING SENSITIVE BIOLOGICAL PRODUCTS

Why gentle fluid handling matters

Antibodies can be sensitive to shear, air–liquid interfaces, pressure changes and interactions with processing surfaces. Some ADCs are additionally susceptible to aggregation because of their hydrophobic payloads. Pumps, tubing, valves and dispensing needles must therefore be evaluated as part of the product's complete process environment.

Low-shear liquid handling: Linestaltic pumping

Originally developed for shear sensitive cellular products 3P innovation's linestaltic pumping technology provides an alternative approach that can be evaluated for controlled handling of sensitive pharmaceutical fluids. Potential applications include antibody-solution transfer, movement of conjugated products, formulation dispensing, small-volume transfers and final filling. Suitability depends on the specific product and complete fluid path, including flow rate, accuracy, pressure profile, material compatibility and hold-up volume. Claims about reduced shear or protein protection require product-specific comparative testing.

From laboratory operation to repeatable manufacture

Manual laboratory techniques often rely on an operator's judgement. Automation must reproduce the relevant process conditions through measurable, controllable parameters. Changes in tubing geometry, pumping speed or mixing configuration may affect product quality even when the nominal recipe is unchanged.

Before committing to a production machine, we use representative test rigs, instrumentation and structured experimentation at 3P innovation to explore these relationships. This evidence-led development helps manufacturers select appropriate technology and establish robust operating windows.

ENGINEERING PRINCIPLE

Protecting product quality begins with understanding the process.



CONTAINMENT & ASEPTIC PROCESSING

Two objectives, one manufacturing environment

ADC manufacture can require both protection of operators from highly potent compounds and protection of sterile drug product from contamination. These objectives are different: containment prevents hazardous material escaping, while aseptic engineering prevents contamination entering the product. An effective solution must address both.

Engineering the integrated system

Contained powder and liquid dispensing, closed transfers, sampling, vial manipulation and aseptic filling are potential ADC applications for pharmaceutical automation within isolator environments. At 3P innovation, we design and integrate this automation, including robotic handling, precision filling and material transfer.

Automation, airflow, access, glove arrangements, transfer interfaces, decontamination and maintenance must be considered together. The containment solution should be specified against substance-specific occupational exposure requirements and verified for its intended use. It cannot be understated the benefits that come from an engineering team jointly responsible for the automation and Annex 1 compliant aseptic containment.

Flexible clinical manufacturing

Phase I and II programmes may involve small batches, changing formulations and frequent product changeovers. Modular automation, carefully designed transfer systems and disposable product-contact assemblies may support flexibility while reducing cleaning and cross-contamination challenges.



ENGINEERING PRINCIPLE

Containment cannot be added as an afterthought.

PROCESS CONTROL AND INDUSTRIALISATION

Integrated process control

Repeatable manufacturing systems require mechanical engineering, instrumentation, machine software and automation to work together. At 3P innovation, we combine these disciplines through strategies including precision metering, temperature regulation, controlled mixing, timed sequencing, flow and pressure monitoring, gravimetric or volumetric verification, and batch data acquisition.

Turning a laboratory process into a manufacturing process

Scaling an ADC process requires more than repeating a laboratory recipe. Manufacturers must understand which parameters affect product quality and how those parameters can be controlled, monitored and documented at the intended manufacturing scale.

The transition from laboratory development through clinical trials to commercial manufacture should be an evolution of a proven process, not an exercise in reinventing it. At 3P innovation, we apply this philosophy across our range of benchtop to commercial-scale equipment in our chosen pharma and medtech markets.

Our F2V range of benchtop filling equipment provides a practical starting point, enabling manufacturers to develop, characterise and optimise their dispensing processes using representative technologies and operating principles. Critical process parameters can be established early, providing a foundation for subsequent scale-up. These units can be placed within pre-existing isolators.

As production requirements increase, transfer to our roboFIL automated filling platform should preserve the fundamental dispensing principles and relevant process conditions established during development. Increasing throughput and automation must be assessed against those conditions, rather than assuming that the same process parameters will transfer unchanged. This continuity is particularly important for sensitive ADC formulations, where changes in fluid handling, dispensing dynamics or product-contact conditions may affect product quality.

By maintaining a consistent process philosophy from benchtop development to commercial production, 3P innovation aims to minimise technology-transfer risks, reduce the need for process redevelopment and support a more efficient route through clinical development and into commercial manufacture. Of course, successful scale-up still requires appropriate process verification and validation. However, establishing representative process conditions from the outset can substantially reduce the uncertainty associated with increasing production capacity.

The practical sequence is to prove the process, identify its critical parameters and engineer the automation around them. For manufacturers, this provides a basis for assessing which development conditions must be preserved as production requirements change. From F2V to roboFIL, the objective remains the same: a robust, repeatable manufacturing process, regardless of production scale.

Supporting pharmaceutical innovation

Founded in 2006, 3P innovation is an employee-owned engineering company operating from its UK, Warwick campus. Its capabilities span precision liquid dispensing, powder handling, robotics, aseptic automation, process development, software engineering and custom machine manufacture.

The company specialises in difficult processes, novel products and equipment that does not yet exist as a standard commercial solution. ADC manufacturing- where precise chemistry, sensitive biological materials, containment and reproducibility meet - is a natural area in which to apply that engineering approach.

ENGINEERED AROUND YOUR PROCESS

Successful ADC manufacturing depends on treating precision dispensing, sensitive-product handling, containment and process control as one integrated engineering challenge. Representative development testing establishes the process conditions to preserve; verification and validation demonstrate whether those conditions remain appropriate as automation and production scale increase.

About the Author

Dr Dave Seaward is co-founder of 3P innovation and a chartered engineer with a degree in electrical and mechanical engineering and a PhD in control theory. He has more than 40 years experience developing custom automation across a range of industries, including the pharmaceutical and medical device sectors. Many of his projects have involved advanced powder or liquid dispensing, and he is a named inventor on more than 20 patents.



