



SYRRIS

CASE STUDY

Chemistry automation enables walk-away process development for Alzheimer's drug pipeline

Customer

Scott Clunas, Process Chemist,
TauRx Therapeutics, Aberdeen, UK

Application

Process development of anti-Alzheimer's drugs

Requirements

To simplify and accelerate process development for TauRx's pipeline of innovative products that help diagnose, treat and cure Alzheimer's and other neurodegenerative diseases

Solution

Syrris Atlas HD Automated Jacketed Reactor System

Results

Rapid and reproducible quality by design process optimization workflows

The challenge

TauRx Therapeutics, a spin-out from the University of Aberdeen, is focused on research into Alzheimer's disease, aiming to discover, develop and commercialize innovative products to help diagnose, treat and cure this and other neurodegenerative diseases caused by protein aggregation. An important part of this work is process development, using a quality by design (QBD) approach to investigate a range of parameters that could potentially impact on the quality of the active pharmaceutical ingredient (API). Reproducibility is essential, and automation has a key role to play, eliminating any differences due to manual procedures and ensuring that every experiment is run identically. Scott Clunas explains how walk-away automation with Syrris' Atlas HD batch reactors helped TauRx Therapeutics to simplify and accelerate its process development.

Walk-away automation avoids overnight working

The QBD approach to process development involves the study of parameters such as temperature and time to see what effect, if any, they have on the quality of the end product. Experiments can run for up to 48 hours at a time, and reaction parameters may need to be changed at inconvenient times, sometimes in the middle of the night.

"A lot of experiments involve multiple steps, and manual processes may require staff to come into the lab outside of normal working hours to perform these tasks. With automation, we can simply set up the experiment and walk away, leaving the reactor to run for as long as necessary. Staff realize the benefit of automation and would be reluctant to go back to the original manual processes."

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Atlas HD reactor systems ensure each experiment is performed in exactly the same way every time."

Consistency is everything

During process development, it is vital that experiments are run in exactly the same way each time. The elimination of manual variations is crucial to ensure that any difference in the end product is genuinely due to optimization of the reaction parameters, rather than variations in the way the experiment was performed.

"In a multi-stage process, it is important to implement every step in exactly the same way each time, from changing the temperature to adding precise amounts of reagent at a set time. Automation removes the potential for variation due, for example, to a member of staff being delayed and carrying out that stage of the process at a slightly different time to the one specified in the protocol. This gives us the certainty we need when we are interpreting the experimental results."

The solution

TauRx Therapeutics invested in four Atlas HD jacketed reactor systems, set up as two parallel pairs controlled by a single PC. This has enabled the company to perform QBD studies for the production of APIs more quickly and easily than before.

"We had been successfully using Syrris' Altas Syringe Pumps and software for a number of years, so when we were looking to invest in additional batch reactor systems, the Atlas HD was the logical choice. The Atlas reactor systems ensure that each experiment is performed in exactly the same way every time – eliminating the variability associated with manual processes – giving us a very high degree of process control for consistent results and, ultimately, more robust processes."



"...we can consistently and reproducibly generate APIs, minimizing any waste of time or precious material."

The results

The development and optimization of processes for the manufacture of lead candidates destined for clinical trials entails running a number of experiments, each of which can take between 24 and 48 hours to complete. In this situation, automation of the entire reaction is essential to achieve reliable, reproducible results.

"Automating our processes with the Atlas HD reactors has allowed us to perform QBD studies for the production of APIs faster and more easily. As each experiment is performed in an identical manner, we can be certain that our results are not affected by external influences, such as operator-to-operator variation or human error. This means that we consistently and reproducibly generate APIs, minimizing any waste of time or precious material."

Discover Atlas HD and the benefits of automation at syrris.com/atlas-hd