Batch Manufacture of OPAT by Technical Services

Comisiwn Bevan Commission

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Project Background:

In 2018 Welsh Government published 'A Healthier Wales: Plan for Health and Social Care'. In this document a holistic approach to healthcare was outlined that proposed new models of partnership between providers and individuals that would enable people to minimise their hospital stay.

One treatment pathway that aligns with this framework is OPAT (Outpatient Parenteral Antimicrobial Therapy). This is a method of treatment that uses elastomeric devices to deliver intravenous antibiotics to patients at home.

This service is increasing in popularity yet there are barriers preventing a wider adoption despite the benefits of this method of treatment.

Figure 1: A range of elastomeric devices for OPAT

Project Aims/Objectives:

The aim of this work is to overcome some of the barriers preventing the wider adoption of OPAT by achieving the following:

- Develop a fast manufacturing method for cost effective OPAT devices using semi-automation.
- Carry out stability studies to increase the assignable shelf life of the product.

Figure 2: Semi-automated filling device used during this project.

Project Approach:

The analytical validation, production process design and stability studies were carried out by implementing the principles of QbD (Quality by Design), and guidance set out by applicable regulatory publications.

Project Outcomes:

A Stability Indicating High Performance Liquid Chromatography method was developed for the analysis of flucloxacillin and related substances. A semi-automated manufacturing method has been developed to enable manufacture of 8g/ 240 mL flucloxacillin elastomeric devices by Technical Services in BCUHB.

Stability studies were carried out on the manufactured doses. The outcomes of these studies are summarized in the table below:

Parameter	Before Project	After Project
Manufacturing Time	5 hours	45 minutes
4°C Shelf Life	13 days	42 days
25°C Shelf Life	Not Known	10 days
32°C Shelf Life	1 day	3 days
Cost/ 7 days	£821	£323
Lead Time	Best case 24 hours if ordered before 11 a.m.	Stock item in pharmacy

Project Impact:

This project has developed a production method to produce 8g/ 240 mL flucloxacillin elastomeric devices that can be integrated into the Aseptic Production facilities in Wrexham Maelor Hospital (YMW). By investing **3 hours / week** of manufacturing time and implementing the OPAT manufactured by Technical Services the following savings can be realised across a **12-month** period (assuming one patient per week is treated):

★ **524 Bed Days** ★ **~£368,500**

Key Conclusions:

- The use of automation within hospital aseptic manufacturing units makes the high-volume manufacturing of OPAT devices possible.
- This method of treatment can realise significant benefits to both healthcare providers and patients.
- The findings of this project are supportive of the Welsh Government's vision for the future of healthcare in Wales.

Next Steps:

- Scale-up production to offer a consistent service across BCUHB.
- Increase the range of drug molecules available in elastomeric devices for OPAT.
- Technology transfer between other hospital sites in Wales.

"I would, without a doubt recommend the service to those that meet the criteria to receive it. I think the idea of the service is something that should become more mainstream."

Service User – Patient at YMW