

Reflective account form – industrial pharmacy, purchasing and distribution

1. Provide us with a reflective account of how you met one or more of the standards for pharmacy professionals. We will tell you which standard(s) to choose from each year.

I am responsible for providing Investigational Product (IP) for clinical trials. The standard process is for IP to be shipped to clinical sites from depots. However, this year one of my studies required the option for IP to be shipped from the clinical site to patients at home. No established processes are in place so the study team were forced to develop a process from scratch.

I worked with the team to ensure they considered all relevant aspects of IP shipping but was not ultimately responsible for implementing this process. The study operations team contracted with a specialist courier vendor who had experience with these types of shipments, including knowledge of the regulatory requirements, steps to ensure the necessary chain of custody, and has the capability to operate across a variety of countries and time zones. Part of the process involved providing the clinical site with training on how to educate the patients on this process, including expectations around who the IP could be delivered to (ensuring proper chain of custody). Following implementation of this process, myself and two clinical colleagues wrote a 'white paper' describing the process and challenges that we encountered.

This example demonstrates the importance of communicating effectively with both colleagues and patients to ensure we met regulatory standards and protected patients. There was a need to discuss, agree and document our arrangements for people with different levels of communication skills and understanding of the processes.

There is a description of your area(s) of practice

There is a description the typical users of the service(s) you provide

There is a description how you are meeting one or more of the standards for pharmacy professionals, illustrated with real example(s)