RESPONSIBLE PERSON AND GOOD DISTRIBUTION PRACTICE TRAINING

An interview with Catherine Kay, NSF's Executive Director of Pharmaceutical Services

HOW LONG HAS NSF BEEN PROVIDING GxP TRAINING?

NSF has been providing instructor-led, interactive training programs for over 30 years and has been providing Good Distribution Practice training as a public course for the last two years. We are always keen to have our courses accredited by an independent organization and so applied to have our GDP course mapped against the Cogent Gold Standard.

WHAT IS THE COGENT GOLD STANDARD?

Cogent Skills (alongside the MHRA) have developed a new Gold Standard role profile for a Responsible Person in Medicinal Products. The standard sets an industry-agreed framework that identifies the skills required by a Responsible Person in four areas. This ensures that the role includes not only the traditional qualifications and technical requirements, but also behavioral skills required to do the job to a high standard. These include business improvement, leadership and communication. On completion of the course, all delegates complete an online assessment and following a pass result, receive a certificate from Cogent Skills featuring the MHRA logo.

WHAT ARE THE KEY CHALLENGES FOR THE RP?

At the most recent MHRA GDP Symposium in November, Peter Brown, Senior Medicines Inspector at MHRA, shared the top five deficiencies from GDP inspections in 2018/19:

- Quality Management, 28.5%
- Transport, 21%
- Documentation, 21%
- Responsible Person, 15%
- Risk Management, 13.5%

Quality systems are often not fit for purpose, especially when the company has expanded. The largest contributor of deficiencies in this area is that outsourced activities, such as transportation audits being completed within a two-year cycle, are not being controlled effectively.

Other areas of note are lack of visibility of transport routes and poor export controls, poor documentation, user traceability and missing C88s (single administrative document).

For the second year in a row, the lack of definition of the RP duties and uncontrolled delegation of duties has been a top five deficiency, along with a lack of oversight of commercial matters.

Other emerging trends are the poor understanding of the supply of medicines into territories where there is no license in place, cloned company credentials and falsified GDP certificates from another EU authority.

Overall, IAG (Inspectorate Action Group) and CMT (Compliance Management Team) case numbers are increasing significantly.

▶▶

WHAT IS THE RPI ROLE?

If there is a no-deal Brexit, a wholesale dealer may import Qualified Person (QP) certified medicines from the European Economic Area (EEA) if certain checks are made by the Responsible Person (import) (RPi). The RPi is responsible for implementing a system to confirm that the required QP certification has taken place for products that have been imported into the UK from countries on a list (initially, countries in the EEA).

IS THE TRAINING JUST FOR TRAINEE RPS?

The training is extremely relevant to trainee RPs, but also provides refresher training for current RPs, as well as new warehouse supervisors and managers or personnel who are new to GDP operations, auditors who are expected to inspect storage facilities and personnel from new distribution operations.

ABOUT CATHERINE KAY

Catherine Kay has extensive pharmaceutical operations management, technical and QA experience spanning more than 22 years, gained working for a major international pharmaceutical organization, a start-up manufacturing organization and, most recently, a contract manufacturing organization in a corporate operations role. She joined NSF in November 2017.

Ms. Kay is eligible to act as a Qualified Person under the permanent provisions. She has experience in being responsible for the operational start-up of a new solid dose manufacturing and packaging facility, from design and set-up of systems, procedures and processes to the supply of medicinal products to the global market, meeting EU and FDA GMP regulations and requirements.

Ms. Kay is passionate about developing people and creating learning organizations, with continuous improvement embedded in daily operations.

For more information and to see upcoming dates for our Cogent Gold Standard Approved **Responsible Person and Good Distribution Practice Course**, visit our **website**.

For more information, contact **pharmamail@nsf.org** or visit **www.nsfpharma.org**

Cite as: NSF International. February 2020. Responsible Person and Good Distribution Practice Training. NSF: York, UK.

NSF INTERNATIONAL | PHARMACEUTICAL SERVICES

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF
T +44 (0) 1751 432 999 I **E** pharmamail@nsf.org

789 N Dixboro Rd, Ann Arbor, MI 48105, USA
T +1 202 822 1850 I **E** healthsciences@nsf.org

www.nsf.org I **www.nsfpharma.org** I Follow us on LinkedIn & Twitter

LPH-614-0220