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GMP at the GCP interface: What do non-commercials need to know about GMP to make GCP work?

Traditionally, QA (Quality Assurance) in the non-commercial/investigator-led area focused on one GXP at a time, typically GCP. But with regulatory authorities increasingly being trained to inspect more than area, they are bringing with them a wider remit to their inspections. I have been working with investigator-led clinical trials and GCP for over ten years, and during that time, GCP has mostly been a discipline on its own, with a slight dabbling into one of the other GXP areas. But recently, I was quizzed on GMP during a regulatory inspection and found myself slightly at a loss. We don't manufacture any investigational products on site, but of course re-package and undertake placebo-matching for trials with products bought off the open market. This presentation will cover an overview of the essentials of GMP as they apply to GCP and clinical trials in investigator-led studies.

Biography

Patricia Henley is the quality and governance manager at the London School of Hygiene & Tropical Medicine. Canadian by birth, she completed a biology degree before moving to the UK where she has since completed two further postgraduate degrees, including an M.Sc. in Public Health. She started her UK career in 2001 working in various research roles within paediatric and adult oncology before using her experience in managing clinical trials to develop the Research Facilitator role at Imperial College London, providing operational support and expert advice for all clinical research projects. As well as developing the School's research SOPs and GCP training programme, she has initiated and implemented the School's auditing programme in clinical trials and human tissue. The GCP audits and training sessions have taken her across the African continent in a variety of settings, including teaching and conducting auditing and monitoring activities in French. She has a keen interest in training: as well as being the GCP trainer at LSHTM, she has presented at many national meetings and courses, co-developed a good research practice course with the WHO, and is tutor/module writer for two distance learning Masters Degree courses at LSHTM. She is a member of the RQA, the Research Quality Association, and sits on both the GCP Committee and the Outreach Working Party.

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