Developing and Implementing a Clinical Trials Audit to Improve Good Clinical Practice

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Background

Pharmacy services for clinical trials is a specialty practice area, requiring the application of Good Clinical Practice (GCP) principles by appropriately trained personnel to safeguard patients and ensure the integrity of the research is maintained. Icon Group identified a need to have oversight of the pharmacy services for over 200 clinical trials provided by pharmacies of differing size and capabilities.

Aim

To develop and implement a clinical trials audit program to ensure all pharmacies that are providing services for clinical trials are doing so in accordance with GCP, and have the appropriate regulatory arrangements in place. This program aims to identify areas of the pharmacy that are not compliant with the recommended practice standards, and ensure actions are taken by sites to meet required standards.

Method

Developing the audit tool

The Pharmacy Practice Unit used published standards and guidelines[1, 2, 3] in consultation with experienced clinical trials pharmacists and technicians to develop the audit tool criteria under eight domains (Table 1):

Table 1 Audit Tool – Domains and examples of evidence

Domain	Examples of evidence
Training	Current CV and GCP certificates, and other training records: pharmacy SOP's, trial-specific training
Policies and Procedures	Current pharmacy SOP's: IP receipt, storage and handling, dispensing, disposal
Facilities and Equipment	Fridge and room temperature monitoring, routine equipment maintenance and calibration records
Investigational Products (IP) Storage	Segregated IP storage, appropriate chain of custody from pharmacy to patient/treatment centre
Prescriptions and Labelling	Clear and concise IP prescriptions and dispensing directions (random sample)
IP Accountability	Complete and accurate delegation and accountability logs (random sample)
Regulatory Documents	Pharmacy service agreements, including indemnification; Safety Data Sheets (or equivalent) if hazardous IP
Administrative Processes	IP accurately set up in dispensing ± compounding systems

Each criterion was then enumerated to enable a scoring system which offered a measurable result:

Criterion → **Domain %** → **Overall %**

Criterion	
Numerator / Denominator	
Full Compliance	**2/2**
Partial Compliance	**1/2**
Nil Compliance	**0/2**
Not Applicable (N/A)	**0/0**

Domain %: Total Numerator / Denominator

Overall %: Total Numerator / Denominator

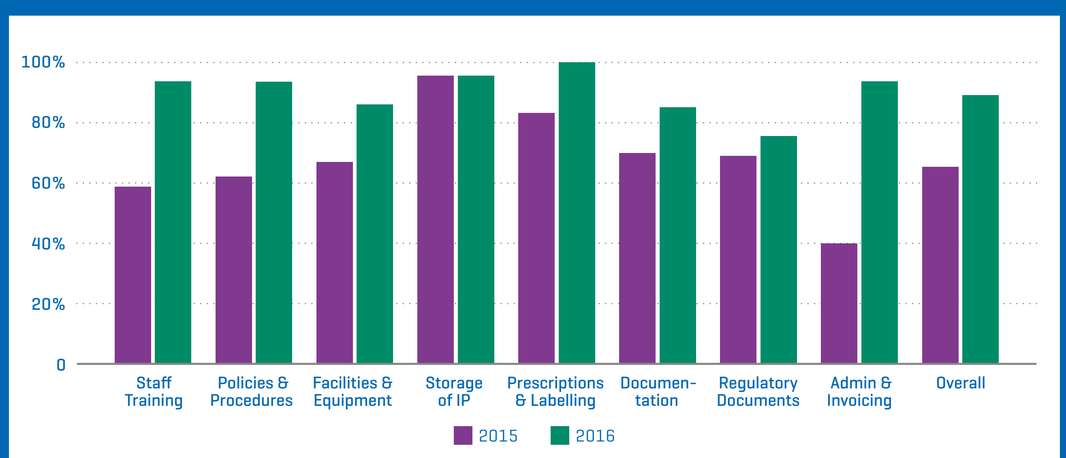
Implementing the Audit Program

A test run of the audit was performed on two pharmacies with different service characteristics to confirm if the tool was effective before extending to the remaining seven clinical trial pharmacies. Upon completion of each audit, a report including an action plan was provided to the pharmacy.

Each pharmacy was given a six month period to complete the action plan and improve the pharmacy's compliance. A second round of audits was then performed to evaluate improvement.

Results

Domain Results as %: 2015 Baseline vs 2016 Re-Audit



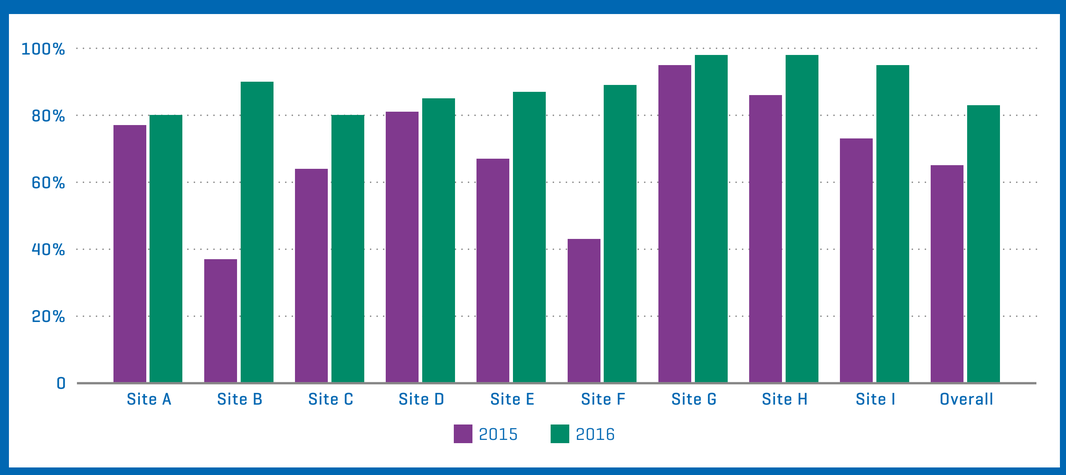
Results from re-audit showed that group-wide compliance improved substantially.
At baseline, domains where overall compliance was greatest:

- IP Storage (96%)
- Prescriptions and Labeling (83%)

Domains that improved the most were:

- Training (from 59% to 94%)
- Policies and Procedures (from 62% to 94%).

Overall Results as %: 2015 Baseline vs 2016 Re-Audit



- It was noted at baseline that the two highest scoring pharmacies (G and H) were resourced with a dedicated clinical trials pharmacist and/or technician to manage higher trials workloads.
- Documentation such as SOP's and other training resources from the higher scoring sites were further reviewed by the Pharmacy Practice Unit and made available for use by all pharmacies.
- The two lowest scoring sites (B and F) were provided with additional support to assist in completing required actions from the baseline audit. For Pharmacy F, this involved site visits by an experienced trials pharmacist. For Pharmacy B, a substantial increase in clinical trials workload between audits necessitated the appointment of a permanent clinical trials pharmacist position.

Conclusion

The clinical trials pharmacy audit program has facilitated improvement in GCP compliance at both a pharmacy and group wide level, based on issues identified during the baseline audit. The audit outcomes also identified a need for a clinical trials pharmacist position with a group-wide responsibility to oversee the quality and consistency of GCP at all Icon Group pharmacies. The audit is now scheduled annually which will ensure ongoing governance of clinical trial pharmacies.

References

1. Therapeutic Goods Administration. Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – Annotated with TGA Comments. Canberra: Therapeutic Goods Administration; 2000. Available at <https://www.tga.gov.au/publication/note-guidance-good-clinical-practice>
2. SHPA Committee of Specialty Practice in Investigational Drugs. SHPA Standards of Practice for Pharmacy Investigational Drugs Services. J Pharm Pract Res 2006; 36 (1): 46-53
3. National Competency Standards Framework for Pharmacists in Australia. Pharmaceutical Society of Australia; 2010. Available at <https://www.psa.org.au/download/standards/competency-standards-complete.pdf>