



IAOCR

The International Accrediting
Organization for Clinical Research

Pharmacovigilance Case Study



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A Symbol of Excellence

Background

- ICON partnered with IAOCR in 2013 to develop a bespoke accreditation for their Drug Safety Associates (DSAs)
- At the time ICON typically recruited from the academic medical/scientific community and trained the staff to be DSAs
- The aims of the program were to:
 - Provide a globally consistent, independently verified standard
 - Ensure that all ICON drug safety staff were able to perform competently regardless of the length of their experience – and **therefore minimize risk to patients and integrity of data**
 - Establish ICON as the global leader in drug safety, thus providing clear differentiation and a dominant position in the marketplace
 - Provide an internationally recognizable accreditation to ICON's drug safety staff



Coordination and Delivery

- The training was delivered by the ICON Corporate Training Department. Trainers and assessors employed by ICON were trained and supported by IAOCR to provide training, competence assessment, and accreditation to over 160 staff in 4 locations globally
- Learners were grouped regionally into cohort groups and attended training from September 2014 to May 2015
- DSAs with less than 2 years experience participated in instructor led training. More senior staff participated in the accreditation program through a portfolio only route
- Registration was through an internal training portal
- Final data was reviewed through this portal by the IAOCR verifier
- Following the initial roll out, the course was embedded as a standard for talent new to ICON





Results and Benefits

Results

- Pre and post program data was gathered from a sample of 41 participants over 1 calendar month intervals.
- Extrapolated figures for 166 staff members completing the program was as follows:

	Pre Program Quality Report	Post Program Quality Report	Improvement	Percentage Improvement
Major Errors	93	16	77	83%
Moderate and Minor Errors	138	97	41	29%
TOTAL	231	113	118	51%

Benefits

- Enhanced reputation as gold standard for drug safety (independently verified by IAOCR)
- Client attraction and retention, due to confidence in drug safety team
- Staff recruitment, engagement and retention – staff feel ‘invested in’ and more confident in their roles