Gerald de Fontenay, J Dev Drugs 2014, 3:3
http://dx.doi.org/10.4172/2329-6631.S1.006

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Summit on
GMP, GCP & Quality Control
September 25-26, 2014 Valencia Convention Centre, Spain

Analytical method lifecycle management

Gerald de Fontenay
Amatsi Group, France

From research to marketing, a drug is controlled throughout its lifecycle with one or several method(s) (in process control, release, etc.). Just as with the drug product itself, the method is built up over several steps. The accumulation of knowledge on its performance will confirm how adequately if fulfils its "intended use", which means the assurance of product quality.

The method validation attests to its performance but its "validated" status should be confirmed during the product lifecycle and particularly when there are modifications to the product, its manufacturing process or in the environment in which the method is used (Analytical Method Transfer and/or Method Verification).

The results history must be integrated into the Product Quality Review (PQR). The follow up of method performance (capability) is also an integral part of this review allowing the best interpretation, with all the actors in drug quality, of any observable trends and their impact on product quality.

Biography

Gerald de Fontenay has completed his PhD in 1995. He directed several preclinical development studies in the pharmaceutical industry before joining Avogadro, a French-based CRO, where he directed the Pharmaceutical Analysis Department during 13 years. He just came back to this company, part of Amatsi Group, in 2014, after 2 years of International Project Management at SGS Life Science Services. He is now Director of the "Pharmaceutical Analysis Solutions" Business Unit across the different affiliates of the Amatsi Group, CRO based in Europe and North America.

g.defontenay@amatsigroup.com