A+ Science Newsletter

“What you do today can improve all of your tomorrows.”

Ralph Marston

It has been a very busy couple of months for us at A+ Science. We clearly see an increased number of inquiries, life science companies are now investing in clinical trials, in other words, contracts are signed, and work has started. We are very happy to be chosen as trusted CRO partner and an extended hand to assist in conducting clinical trials and providing pharmacovigilance services.

Our Head of Pharmacovigilance, Mario Clementi participated last month at yearly Information Day for Pharmacovigilance at Läkemedelsindustriföreningen (LIF), the trade association for the research-based pharmaceutical industry in Sweden.

We asked Mario about the event, and this is what he said: “Since I’m a member of the Experts Network for PV at LIF, I had the pleasure to help organizing this event in collaboration with Julia Appelskog, currently EU QPPV at Novavax, and Linda Melkersson from LIF. We thought that it would be interesting to hold a presentation about inspection readiness and so we invited Helena Tidlund from Pharma Relations. Helena spoke about her personal experiences when she previously was employed at the Swedish MPA as a PV inspector. At the time I had interacted with her in my role as QPPV during a couple of PV inspections. Therefore, we were both able to share some good examples to the audience from real life, but from two different point of views. After that Julia Appelskog held an interesting presentation on inspection readiness from a MAH perspective.

I would say that our common take home message was that inspection readiness is all about putting patient and population safety in the first place, by ensuring to have robust PV processes in place".

We wish all our readers a wonderful and relaxing summer!

Contact us at info@a-plusscience.com to find out more about how our team can help you reach your goals and objectives.

Are you aware of the services A+ Science provides?

- Our services include clinical trial management, we can conduct the entire clinical study, from start to finish or parts of it, depending on our customers' needs.
- We also provide full pharmacovigilance services, pre-and post-marketing, including 24/7 availability of QPPV, Deputy QPPV and Drug Safety Physician, safety database license including MedDRA license, ICSR processing (pre-and post-marketing) including medical review and submission to Eudravigilance and MHRA, Regulatory intelligence, literature search and review (global and local), ICSR collection from EVWEB,

monitoring of MHRA ICSR portal, XEVMPD and PSMF maintenance, signal management, writing of SOPs, PSURs, DSURs and RMPs.

- We can empower your team by outsourcing personnel (short- and long-term solutions).
- Since 2004, we offer services within Continuing Medical Education (CME) in collaboration with University Hospital of Umeå and the Sahlgrenska Academy, University of Gothenburg.

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