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ROCHE/RQA COLLABORATION: IMPACT OF THE CERTIFICATE IN DATA BASICS eLEARNING IN THE PHARMACEUTICAL INDUSTRY, INCLUDING THE LAUNCH OF THE IMPALA CONSORTIUM


MPALA

Launched back on the 21st April 2021, Roche and the Research Quality Association partnered together in a new industry collaboration to bring its members the Certificate in Data Basics eLearning course, which is part of Roche's Data Analytics University.

The course was designed to equip quality professionals with:

- The basic analytical skills and knowledge they need to interpret and use data effectively
- Recognising the challenges of data processing and analysis
- Describing different statistical methods used to interpret and analyse data
- Practical application by using statistical methods on a simplified data set
- Developing critical judgement when it comes to data, statistics and visualisations.

The self-paced learning course which takes approximately three hours to complete, includes a final self-assessment knowledge check which, when successfully passed, enables you to collect three CPD points.

Since its initial launch back in 2021, a total of 284 RQA members have enrolled to take the course, with 152 completing the training to date. Based on the demographic characteristics of current RQA members who would be likely to take the training, just under half – 44%, have either enrolled or taken it so far.

With that in mind, Roche and the RQA began assessing what impact the Certificate in Data Basics eLearning has had in the pharmaceutical industry since its launch and how we can broaden our reach with this eLearning to other quality professionals across industry.

'Overall 96% of RQA members would recommend this course to their colleagues.'

IMPACT

Reviewing the initial end of course survey feedback provided by quality professionals indicated a positive response to the eLearning:

- 97% said they will prioritise implementing the course concepts into their work
- 88% said that the eLearning will help them improve their work outcomes
- Overall 96% of RQA members would recommend this course to their colleagues.

Building on this, we contacted RQA members that had completed the course to hear what impact the training has had on their work and the changes they have made as a result.

> *Taking this course has helped me with supporting my clients in preparing for inspections, especially with reference to the statistics part of inspections as it has given me a better understanding of the terminology and principles of data handling.*
>
> **Helen Powell from HYP Pharma Ltd, Pharmacovigilance and GCP QA Consultancy**

> *The course provided me with a good revision of basic statistics and is a helpful reference point for me when auditing clinical lab data.*
>
> **Gail Todd, Associate Director LabsQA, AstraZeneca**

> *I applied what I learned towards the assessment of R and its use in data analytics at Flatiron. I was able to partner with the Quantitative Sciences (QS) team to develop and implement a risk-based framework. The course provided me with the basics which I was able to use in discussions with the QS team to further my knowledge about data analytics.*
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> **Manan Patel, Manager, Integrated Quality Management, Flatiron**

Other feedback obtained said that it helped '*give non-data scientists an understanding of how data analytics works*' and that they '*really enjoyed putting the insights learnt into practice*'.

'We hope to inspire and spark an interest with non-members for them to continue with learning and benefit from training like RQA members have.'

Carl Lummis, Events, Marketing, Publications and Online Learning Manager at RQA summarises that *"The eLearning course has helped bring a stronger, more diverse perspective to Data Basics for RQA members. This initiative has given all members involved a new opportunity for growth in this area".*

The insights derived from the data points collected indicates that the eLearning course is being utilised by a mixed group of people for varying activities, that most quality professionals were making or had made changes as a result of taking the eLearning course and that it was making a positive impact for those who had. In conclusion, the data supports that the course concepts are indeed making an impact in industry. Roche aims to be industry leaders in this space and with the support of the RQA have made great inroads to achieving this.

BROADENING OUR REACH

To build on the great response and uptake of the course by RQA members, Roche are now looking to gain a wider audience and global reach of other quality professionals across industry, outside of the RQA.
As a result, Roche and the RQA have collaborated to release the first three parts of the Certificate in Data Basic eLearning free to non-members*. The courses, which are available to access on the RQA website, are:

- Introduction: Welcome to the Course
- Chapter 1 – Demystifying Analytics – Part 1
- Chapter 1 – Demystifying Analytics – Part 2

By taking these short, self-directed courses, it will give quality professionals a basic introduction to data analytics and provide a good platform to build upon. We hope to inspire and spark an interest with non-members for them to continue with learning and benefit from training like RQA members have. In turn, Roche will achieve its objective to broaden their reach to other quality professionals across industry.

LAUNCH OF IMPALA CONSORTIUM

Continuing on the theme of data analytics, Tim Menard shares his insights into the newly launched Inter-Company Quality Analytics Industry group (IMPALA) and what that means for RQA Members.

WHAT IS THE INTER-COMPANY QUALITY ANALYTICS INDUSTRY GROUP (IMPALA)?

The Inter coMPany quALity Analytics (IMPALA) consortium was initially established in July 2019 as an informal group of biopharmaceutical organisations with the common goal to share knowledge and better understand opportunities in applying advanced analytics for QA.

IMPALA's mission is to transform the Biopharmaceutical Clinical Quality Assurance process in the Good Clinical Practice and Good Pharmacovigilance Practice areas, by using advanced analytics and promoting the adoption of this new approach and associated methodologies by key industry stakeholders (e.g. pharma quality professionals, health authorities) to assure safe use and therefore building patient trust, accelerating approvals and ultimately benefiting patients globally.

The IMPALA consortium will provide the strategic focus for working across the biopharmaceutical ecosystem to develop and gain industry-wide consensus for the adoption of improved QA using advanced analytics and best practices to be used across the industry.

To achieve this, several Work Product Teams have been established and are currently working on focused projects to advance the IMPALA consortium's objectives. Current members include Astellas, Bayer, Biogen, Boehringer Ingleheim, Bristol Myers Squibb, Johnson & Johnson, Merck KGaA, Merck & Co., Novartis, Pfizer, Roche and Sanofi.

WHAT WOULD RQA MEMBERS WANT TO KNOW ABOUT IT?

IMPALA are committed to developing an open source product (i.e. co-development of open source tools: analytics packages, templates, methodologies, etc.), meaning once these work products are released, they are accessible beyond IMPALA members. Our current work products are auditing schedule, data integrity, anomaly detection in audit trial and quality briefs, more information on these can be found on our website.

HOW CAN RQA MEMBERS GET INVOLVED?**

Some RQA members may remember that IMPALA ran an interactive session 'How can we leverage data analytics for clinical quality and accelerate drug development? at the RQA International QA Conference back on 10th November 2022. The IMPALA panel engaged with the audience to define, discuss and gather business requirements for data analytics use cases in clinical quality. RQA members can continue to get involved in the discussions as IMPALA plans to attend the next RQA conference in November 2023 for another interactive session. More information to follow.

On 26th June 2023, as part of the DIA Global Annual Meeting in Boston, MA, IMPALA will present:

1. The vision of IMPALA and examples of IMPALA's quality analytics products.
2. Ongoing feedback from health authoritieson the quality analytics methods.
3. Guidance on how sponsors and regulators can join IMPALA. At a fee, RQA members are welcome to attend and more information can be found on the DIA website. *www.diaglobal.org*

WHERE CAN RQA MEMBERS FIND OUT MORE INFORMATION?

To keep up to date on the latest news, RQA members can follow IMPALA's LinkedIn page: *www.linkedin.com/company/inter-company-quality-analytics*. They can also head over to IMPALA's website, which has a wealth of information on work products, publications and upcoming events: *https://impala-consortium.org/*

* In order to take the remainder of the eLearning course they will need to sign up to become RQA Members.

**Please note that at this time, only Bio Pharma organisations are eligible for membership to IMPALA. Biopharma sponsors can apply to join via the IMPALA website.

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PROFILES

Sharon is currently a Principal Quality Solutions Lead at Roche, responsible for leading and delivering the Data Analytics Learning Strategy for her function. She has been working in the pharmaceutical industry since 2006, holding a variety of positions in Quality Assurance from Lead International Clinical Auditor to Quality Assurance Specialist, gaining extensive experience across the GxP disciplines. Sharon holds a Diploma in Learning and Development and is an ILM Accredited Advanced Professional Trainer.

Tim is currently Head of Quality Data Science at Roche. He started his industry career in 2009 in PV with different roles (operational and strategic) that brought him to live in various parts of the world. Tim joined Roche as an auditor and dived into the 'magic world of analytics' somewhere in 2017. He has been leading the PDQ Data Science Team at Roche since 2018 and his team is creating and implementing data-driven solutions that help understand, early detect or predict clinical quality issues.