3C Integrity’s Serialisation Workshop - September 2015 - Basel

Why 3C Integrity’s Serialisation Workshop?
• 2015 is a turning point in global Serialisation and Traceability Requirements as the impact of the US DQSA become clearer, the adoption of the EU-FMD Safety Features Delegated Act is expected and the scope of the requirements in other markets is assessed.
• It is now clear that by 2018 over 80% of a typical Pharma Company’s sales will be subject to Serialisation Requirements and that manufacturers can no longer delay their Serialisation Readiness Programmes
• 3C Integrity’s Serialisation Workshop, informed by years of practical experience, addresses this industry-wide challenge by delivering clear and practical guidance on how to get started. As part of the Workshop, unique high value content will be delivered that allows delegates to kick-off, scope and budget readiness programme, putting them in the best possible position for a perfect start.

Why is this Serialisation Workshop special?
• 3C Integrity’s approach starts and ends with the manufacturers’ perspective.
• Our company is independent of solution or vendor and can therefore give unbiased advice.
• The trainers - Christoph Krähenbühl and Ian Haynes – are uniquely qualified and widely recognised as “Serialisation Gurus”, experts and thought leaders in coding and serialisation for the pharmaceutical industry.

Practical Matters
• The scope of the Workshop event is global / international: All currently active global serialisation and traceability requirements will be covered
• In order to allow for optimal engagement and lively interaction, the number of attendees will be strictly limited to a maximum of 30 delegates
• The Workshop and materials will be delivered in English

Target Audience
• Any pharmaceutical company involved in the production of pharmaceutical packs / traded items, including contract manufacturer, re-packerager and parallel trader and companies producing original / branded products or generic products.
• Companies that have not yet started their serialisation programme or are in their early stages and are seeking validation that their programmes will deliver their strategic goals
• Serialisation project team: Project managers, subject matter experts and key members of cross functional project, typically representing Manufacturing Operations, Engineering, IT/IS, Regulatory
• This Workshop is also ideal to facilitate rapid on-boarding of new team members
Course content

The Workshop course addresses the key areas of any manufacturer’s readiness programme:

- Analysis of key legislative requirements
- Defining a strategic approach
- The technology stack and beyond
- Building user requirements, vendor selection and vendor management
- Compliance / CSV considerations
- Serialisation case studies
- Cost considerations and costing models
- Moving from project to Business as Usual

Learning Goals

Delegates will leave the event equipped with

- A solid understanding of the key components of their readiness program
- Good, practical, step-by-step advice on how to implement your project.
- A pack of ‘how to get started’ material
- How to scope the serialisation project requirements of their particular organisation
- Achieving initial and on-going buy-in and support from all key stakeholders

Delivery method / Course Structure

Each event will be run over two full days, consisting of a mix of presentations and interactive workshop sessions with plenty of Q&A opportunity, all centred around a structured curriculum that moves from the strategic scene-setting, requirements definition to the practical, hands-on challenges of project implementation and go-live.

Presenters / Panel

Ian Haynes and Christoph Krähenbühl, the partnership behind 3C Integrity, will be your main presenters. They are highly experienced professionals with extensive knowledge of product security, coding and serialisation solutions in the pharmaceutical industry. Many years’ practical experience in live manufacturing environments, combined with involvement in major initiatives in this area (EFPIA, ESM), ensures a well-informed perspective on the complexities of serialisation.

Date and place of course

Tuesday 19th and Wednesday 20th May 2015 at the Vitra Campus, a prestigious venue near Basel, within short travelling distance of

- EuroAirport Basel-Mulhouse-Freiburg,
- Basel SBB and Basel Bad Bhf Railway stations
- Autobahn A5 (Germany), A2 and A3 (Switzerland) and Autoroute A35 (France)

Registration and further information

- Regular delegate fee is €1890.00 (+ VAT where applicable) payable in advance; this includes working meals, refreshments and take-away course materials
- For more information contact the events team for more information: events@3Cintegrity.com