

*Setting the Standard for Automation™*



# The business of buying Serialisation

From a Suppliers perspective

Standards  
Certification  
Education & Training  
Publishing  
Conferences & Exhibits

- Owner Founder of Crest Solutions 18 years ago
- 100+ people across 5 offices in Northern Europe
  - Irl, UK, Benelux, Scandinavia
- Heavily involved in Serialisation for the past 11 years
- Exclusive Partner of Antares Vision the worlds largest Serialization provider (700+ serialised Lines installed)
- Global supplier to companies like MSD, Allergan, Gilead, Leo Pharma, Sanofi, PCI, Abbvie, Abbott, J&J, Teva and the majority of the other top 20 Pharma companies
- We are currently Installing and commissioning 50 lines



**C R E S T**  
S O L U T I O N S

# •OUR LOCATIONS



• Little Island



• Mechelen



• Westport



• Corby



• Mölndal



# • TYPES OF COMPANIES WE WORK WITH



## •BUILDING A SERIALISATION BUSINESS:

### •The good old days

- Became the Antares exclusive partner in March 2012
- We were a competent Machine Vision Solutions company at that time
- Were used of GAMP and the Pharma Industry
- .. But we had no idea what was about to hit us
- .. At the time we had no project managers, no team structure, no dedicated documentation department, no dedicated trainers, 27 people, 1/5<sup>th</sup> turnover,

- BUILDING A SERIALISATION BUSINESS:
- Serialisation effects everything in the business



MAN

- Skills and knowledge of Management
- Skills and knowledge of Implementation team
- Resources, resources, resources
- Skills of technical support staff
- Skills of operators and Line Managers
- Skills in System solutions rather than point solutions
- Cross functional teams from planning to warehouse

- BUILDING A SERIALISATION BUSINESS:
- Serialisation effects everything in the business



- Artwork changes on every carton
- Changes to most of the packaging materials
- Changes to Labelling
- Perhaps changes to existing label processes (sap labels)
- Changes to bundling and case packing materials operations

- BUILDING A SERIALISATION BUSINESS:
- Serialisation effects everything in the business



- Just Serialisation or Serialisation and aggregation?? Big difference.
- Changes to Lasers and printers at cartoning
- New Machines to print and verify or integrated alternatives
- Changes to Bundling, case and pallet operations
- New IT infrastructure, More servers, MES and Level 4 integration
- Plant wide control software requirements
- Speed of the lines important consideration



- BUILDING A SERIALISATION BUSINESS:
- Serialisation effects everything in the business



- Complete change to how the lines are run
- Changes to how the lines are supported
- Professional comprehensive training required
- Changes to how product moves in the factory
- Changes to how production planning works
- Change to how lines are validated

- BUILDING A SERIALISATION BUSINESS:
- The deployment model that works for us

- Move from a client vendor to a partner model
- The concept of workshops
- Local support and control is vital (the market is very busy)
- Collaborative team based approach
  - We have a six man team minimum for every installation
    - Local PM, Remote PM, Documentation engineer, SME, Installation engineer, Customer Manager



- BUILDING A SERIALISATION BUSINESS:
- Training and Skills are Key

- Training is key for both customer and supplier
  - Introduced training academy
    - Full packaging line & separate serialisation line on Site in Cork
  - 12 week packaging course on actual Pharmaceutical line
    - Covering Serialisation, Vision, GMP and Automation
    - Designed for customers technical staff and graduate engineers
  - Introduced 12 and 24 month Apprenticeship (12 months in Italy)
  - Full Serialisation Certification programme from July 1<sup>st</sup>
  - Fill online portal for competence based training for our customer

- BUILDING A SERIALISATION BUSINESS:
- The deployment model that works for us

- Knowledge and skills are critical
- Customers should employ or contract experts
  - Pms, Process engineers, Validation people, IT specialists
- Training is key for both customer and supplier
  - Introduced training academy
    - 12 week packaging course on actual Pharmaceutical line
  - Introduced 12 and 24 month Apprenticeship (12 months in Italy)

- BUILDING A SERIALISATION BUSINESS:
- The deployment model that works for us

- Serialisation is not just for Christmas
- Long term partnership
- Embedded Engineers from supplier
- Training and on going certification is critical
  - On line learning portal, demo Lines, seminars and learning environment
  - Introduced training academy
  - SLAs are key with strong local support as well as remote assistance



- BUILDING A SERIALISATION BUSINESS:
- The deployment model that works for us

- Communications is Key
- Daily contact between PMs
- Weekly Project calls (Italian/Irish Support personnel and customer)
- Monthly Steering group committee meetings
- Quarterly Global steering group meetings
- Clear lines of communications and escalation processes



•FEAR NOT!

A photograph of a hand reaching upwards towards a bright sun in a blue sky with clouds. The sun is positioned behind the hand, creating a lens flare effect. The text is overlaid on the image.

**THERE IS LIGHT  
AT THE END OF THE TUNNEL**

- BETTER LANDSCAPE
- FUTURE PROOFING

- Supplier companies are mature in the implementation
- Technology is maturing
- Legislative landscape is becoming more fixed
- The general skill levels in the industry are maturing

## Main Caution

- There are a lot of advisors on the client side but very few vendors and little chance of many new suppliers. Make sure you are not leaving it to the last minute to implement Serialisation. The impact of the European Directive decision is massive.