making excellence a habit™
Consultant Event 22\textsuperscript{nd} October 2013: Welcome

- Welcome to BSI
- First UK event for Consultants, hopefully not the last
- Strong partnerships with Clients and Consultants
- Share information and latest regulatory developments
- Discuss topics of interest to you and your clients
- Network with BSI and other Consultants in an informal setting
- Open a forum for future discussions and meetings
- Housekeeping
# Consultant Event 22nd October 2013: Agenda

<table>
<thead>
<tr>
<th>Start</th>
<th>Finish</th>
<th>Speaker</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.15am</td>
<td>10.30am</td>
<td></td>
<td>Coffee and registration</td>
</tr>
<tr>
<td>10.30am</td>
<td>10.35am</td>
<td>Damon Williams</td>
<td>Welcome, introduction and housekeeping</td>
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<tr>
<td>10.35am</td>
<td>11.00am</td>
<td>Anna Sadio</td>
<td>IVD Directive changes and what it means in practice</td>
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<tr>
<td>11.00am</td>
<td>11.30am</td>
<td>Sharmila Gardner, Steve Ward</td>
<td>Telehealth: CE Marking: Stay Mobile through the regulation maze</td>
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<tr>
<td>11.30am</td>
<td>12.00pm</td>
<td>Itoro Udofio</td>
<td>Ortho-Spinal re-classification and impact</td>
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<tr>
<td>12.00pm</td>
<td>1.00pm</td>
<td></td>
<td>Lunch and Networking Opportunity</td>
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<tr>
<td>1.00pm</td>
<td>1.30pm</td>
<td>Vicky Medley</td>
<td>Unannounced visits - coming sooner than you think</td>
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<tr>
<td>1.30pm</td>
<td>2.00pm</td>
<td>Marie Eve Cluzel, NAMSA</td>
<td>A practical approach to clinical evaluation that fulfills the future EU regulation expectations: principles and examples</td>
</tr>
<tr>
<td>2.00pm</td>
<td>2.15pm</td>
<td>Damon Williams</td>
<td>Consultants List, understanding BSI and how we can help you/your clients</td>
</tr>
<tr>
<td>2.15pm</td>
<td>2.45pm</td>
<td>Neil Adams</td>
<td>MDD changes and impact on UK medical device companies</td>
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<tr>
<td>2.45pm</td>
<td>3.00pm</td>
<td>Various</td>
<td>Q&amp;A Session</td>
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<tr>
<td>3.00pm</td>
<td>3.30pm</td>
<td></td>
<td>Coffee, networking and close</td>
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Why bsi?

Introducing BSI – Medical Devices

Damon Williams - Business Development Manager
BSI – who are we?

• Established in UK in 1901

• Now operate in over 129 countries

• 54 offices globally

• 2,645 staff worldwide

• Standards, Testing, Training, Assessment and Notified Body
Our Value Proposition

5 Core Reasons to Choose BSI

• **Product Expertise** – our diverse and experienced team brings in-depth knowledge and understanding of complex medical device technologies

• **Global Access** – we operate in over 100 countries with more than 100 years of experience and offices around the world to serve you

• **Speed-To-Market** – providing flexible solutions for manufacturers needing accelerated pathways to global markets

• **Confidence** – our stringent review process combines speed with experience, integrity, independence and predictability

• **Partnership** – we focus on establishing a partnership with each client so we can work together to meet their goals
BSI – Trusted Partner

- Leading Notified Body
  Top 3 Worldwide
  Accredited by MHRA (UK)
  FDA (US), CMDCAS
  (Canada) and JPAL (Japan)

- No 1 in US and UK

- BSI clients include 72% of the top 50 Medical Device companies ranked by annual revenue

- Strength in High Complexity Medical Device sector eg cardiovascular and orthopaedic implants, IVD & Active Devices

- 23 of the world’s top 25 global medical device manufacturers choose BSI as their Notified Body for CE marking certification
BSI Commercial Awareness: Speed – To – Market

• CE-90 Standard Service

• CE-45 Fast-Track

• On-Site Fast-Track

We provide flexible solutions for manufacturers needing accelerated pathways into the marketplace.
BSI - Process

Information Gathering (CIF), Device Classification, BSI Proposal (Quote), Acceptance by Client, Allocation of Scheme Manager, Scheduling of Audit Dates

<table>
<thead>
<tr>
<th>Technical File or Dossier Review</th>
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<tr>
<td><strong>Standard</strong> (90 working days from start to certificate)</td>
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<tr>
<td><strong>Fast</strong> (45 working days from start to certificate)</td>
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<td><strong>Dedicated</strong> (45 working days from start to certificate)</td>
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<tr>
<td><strong>On Site</strong> (45 working days from start to certificate)</td>
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Responses and Questions Cycle

Timelines depending on service offered

<table>
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<tr>
<th>Close out of Questions</th>
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<tbody>
<tr>
<td>Questions close out</td>
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<tr>
<td>Finalised panel forms</td>
</tr>
<tr>
<td>Recommendation for Final Certification</td>
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<tr>
<td>Scheme manager counter signature</td>
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Panel Review

Stage 1: 5 days

Stage 2: 5 days

Issue of Certificate
BSI - Support Services

Training portfolio

• ISO 13485
  • Introduction
  • Implementation
  • Internal auditor
  • Lead auditor

CE marking

• Introduction
• Implementation
• PMS & Vigilance
• Drug-device combinations
• In-vitro diagnostics

• ISO 14971 risk management
• Process validation for medical device industry

Public, in-house, tailored, web-based
Build from Notified Body experience
Continued investment in quality and competence
## Consultants List 2013

### Advena Medical
- Pure Offices, Suite 35
- Plato Close, Tachbrook Park
- Leamington Spa
- Warks
- CV34 6WE

### Contacts
- **John Adcock** 01926 800153
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- **Kirstie Ostle** 01926 800153
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  - http://www.advenamedical.com

### Services
- Regulatory Services
- Quality Management
- Medical Device Design
- Cosmetic Regulations
- Company Secretarial Services

### Summary
At Advena, we are dedicated to providing the most efficient and cost effective service available to ensure client’s success.
Contact Us

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