Meeting Agenda:

**October 5, 2016**

8:30 – 9:00 am  **Registration, Check-In and Continental Breakfast**

9:00 – 9:05 am  **Welcome and Introductions**

9:05 – 10:00 am  **Complaints – Definitional Questions**  
*Linda Chatwin, Esq, RAC, Manager Medical Regulatory Advisory Services, North America, UL LLC*

- What is a complaint?
- How do you distinguish among a product complaint, a satisfaction complaint and a customer inquiry?
- What is a service call?
- What is the difference between a service call and a complaint?
- When are service calls complaints?
- Does the FDA differentiate an instrument repair from a complaint?
- Should companies document all service calls as complaints?

10:00 – 10:45 am  **Setting Up a Complaint System**  
*Linda Chatwin, Esq, RAC, Manager Medical Regulatory Advisory Services, North America, UL LLC*

- What are the elements of an effective complaint management system?
- How does risk management influence complaint handling decisions?
- What department within a company should have primary responsibility for the complaint management system?
- How do service and sales calls fit into your complaint handling procedures?
- How do you motivate your Service and Sales personnel to report complaints?
- How do you train your Customer Call Center employees to identify complaints while talking to the customer on every-day issues?
- What are the responsibilities of other departments?
- What is the best way to train customer contact employees?
- Where should the files be maintained, who should maintain them, and for how long?
- What is the relationship to your CAPA system?

10:45 – 11:15 am  **Break**

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11:15 – 12:00 pm  Handling Complaints & Trending  
*Kim Platt, Senior Principal Specialist, Operations Manager, R&Q*
- Why is it important to establish a process for handling complaints?
- What are examples of SOPs for sorting out potential MDRs and product complaints?
- What steps would the FDA expect to see the departments taking that sorts out potential MDRs, product complaints and other reportable events?
- How do you perform trending?
- What are examples of how companies trend and analyze service calls and product complaints?
- Are companies required to trend resolution to complaints as well as complaints?
- What is FDA’s expectation about trending complaints from non-US markets?

12:15 – 1:00 pm  Lunch

1:00 – 2:00 pm  Recalls and Other Field Actions  
*Novasyle*
- What is the clinical context for recalls and other field actions?
- Who should be involved in the decision process?
- Who should be responsible for communicating with FDA?
- What are the consequences of a recall?
- What factors should you consider when determining whether or not to get your product back?
- How do you prepare for a post recall inspection?
- What customer and other outside communications are necessary?
- What documentation should be prepared?
- How should the product liability implications of recall communications be handled?
- What is an effectiveness check?
- How should you write your recall correspondence?
- How do you determine that your recall is completed?
- What do you do to close your recall internally and with FDA?

2:00 – 3:00 pm  Understanding MDRs  
*FDA (Invited)*
- What are the key terms, definitions and forms?
- How should you investigate complaints to determine if they are MDRs?
- What constitutes a reportable malfunction or MDR?
- What does an MDR flow chart look like?
- Coding
- How do you conduct risk assessment?
- When should you not report an incident?
- If you make an MDR report do you also have to report under 21 CFR Part 806?
- Are there any steps in between?
- How do you manage international reporting requirements under your complaint handling system?
- Is ‘Summary Reporting’ appropriate?
- What about other alternative reporting mechanisms?

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3:00 – 3:15 pm  Break

3:15 – 4:15 pm  Q&A with the FDA
    FDA (Invited)
    - FDA’s point of view on how they see the regulations
    - Clarification points on any relevant regulations of interest from the audience

4:15 – 5:00 pm  An Introduction to Health Hazard Evaluation (HHE)
    Kim Platt, Senior Principal Specialist, Operations Manager, R&Q
    - What is a Health Hazard Evaluation
    - When should an HHE be initiated
    - What are the elements of a well-documented HHE
    - What are the common mistakes
    - How are they documented
    - Who should approve
    - How are records maintained
    - What is FDA’s involvement in health hazard evaluation and classification

5:00 – 6:00 pm  Networking Reception

October 6, 2016

8:30 – 9:00 am  Continental Breakfast

9:00 – 10:00 am  Part 806 Reports of Removals and Corrections
    Kim Platt, Senior Principal Specialist, Operations Manager, R&Q
    - Relationships between MDRs, Corrections, Removals, and Recalls
    - What are the key elements of 21 CFR Part 806?
    - What are examples of items that need to be reported?
    - Should you file an 806 if you have a recall or advisory notice?
    - What information needs to be reported?
    - What types of records do companies need to keep?
    - Prior to notifying FDA, what steps should you have taken?
    - What are the dos and don'ts when informing FDA of a product problem?
    - Should you have a different strategy for removals and corrections than for recalls?

10:00 – 10:15 am  Break

10:15 – 11:15 am  Current FDA Inspection & Enforcement Trends
    - FDA perspective on post-market issues and field actions
    - Current enforcement trends
    - FDA inspectional activities
    - FDA expectations for the industry

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11:15 – 12:15 pm  Measuring the Effectiveness of Your Complaint System  
Kim Platt, Senior Principal Specialist, Operations Manager, R&Q  
- What is an appropriate complaint handling system in a risk-based post-market environment?  
- How do you audit a complaint handling system?  
- From your audits, how do you judge that your complaint handling system is effective?  
- How do you ensure that your electronic records database handling complaints complies with 21 CFR Part 11?  
- How do you perform a failure investigation and what documentation would you maintain?  
- How do you investigate complaints when samples are not available or product is not returned?  
- What guidelines should you provide to your employees about how and when to respond to customer complaints?  
- How to get the data and what to do with it

12:15 pm  Adjournment