**Exclusive Digest – Workshop Leader Interview with Steven Badelt**, Founder and Managing Partner, **Suttons Creek, Inc.**

# Combination Products Lifecycle Management Summit 2018

In the lead-up to our Combination Products Lifecycle Management Summit (June 19 – 21, Boston), we have caught up with **Steven Badelt**, Founder and Managing Partner at **Suttons Creek, Inc.** for his exclusive insights on how the industry is evolving, and what lifecycle management means in the combination products space.

Steven is a seasoned expert in product development, engineering management, business development, and systems engineering. He has over 20 years of experience in the design and launch of combination products and medical devices, including auto injectors, insulin pumps, implantable defibrillators, wireless platforms, and patient management software.

***HW**: Over the last 12 months, "combination product" has become a real buzz word in the industry. There are, however, still a lot of challenges – from technical to regulatory to commercial – but where do you see the biggest opportunity and what's the major barrier?*

**SB**: The answer to both is the development and implementation of an effective product development process. Pharmaceutical companies are working through the nuanced integration of the design-control product development process for devices when merged with the more traditional product discovery process for drugs. Even before 2013 and the introduction of the combination product rulings, the pharmaceutical industry has been following through Tuckman's organizational development model: Forming, Storming, Norming, and Performing.

> *The fact that the industry is now having discussions focused on product lifecycle management (PLM) is an indication of its maturation… However, LCM should be considered and integrated as early as possible in development, hands down, and cover everything from portfolio management to sustaining engineering.*

Naturally, each pharma company is in a different stage of that process. Many startups are just now forming, and often outsourcing, development of the device constituent part. Larger pharma companies may be further along in their organizational development, but they are now progressing through norming to performing.

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***HW***: *Lifecycle management is obviously a complex subject and involves multiple teams internally. What's the common pitfall? And what's your best tip?*

**SB:** Lifecycle management involves responsibilities of many parts of the organization, and organizational change is hard.

The device organization can be thought of as a small startup company within a larger corporation. The procedures for a device team need to not only be instituted within the device organization, but also be integrated within the larger whole of the pharmaceutical organization. This means that adjacent teams in primary/secondary packaging, manufacturing, labeling, regulatory, and complaints handling must change to be compliant and effective. That's a lot of organizational optimization when $3B/year ($8M/day) programs are moving through the process. Drug company alliances and global multisite programs will also add to the complexity.

*Educated executive sponsorship is key. Pharma executive teams are almost exclusively made up of people with a "drug background." Educating executives on the nuances of device development and lifecycle management is critical.*

Educated executive sponsorship is key. Without it, organizational change is slow and suboptimal because it is limited to the "jurisdiction" of one portion of the organization. Consider what it might take for early-stage drug development teams to culturally "know" to consult their device counterparts about formulation strategies. Without early consideration, the device team is left with a constraint around a preselected primary container. In parallel, manufacturing must also be part of the discussion to prevent expensive changes to fill-finish. Integration across all of these functions is how lifecycle management is optimized.

The pharma organization needs to realize and recognize who is the common management decision maker for device integration. In many organizations, the only manager in common with the director of device engineering and the director of quality is the CEO. Pharma executive teams are almost exclusively made up of people with a "drug background." Educating executives on the nuances of device development and lifecycle management is critical. An outside perspective is often helpful, and there have been a number of recent "steals" of high-level talents from one company to another to gain that perspective. The other solution is hiring a consulting organization to provide external expertise and perspective.

***HW***: *Given you've worked with both US and European markets, what's the major difference when it comes to combination products?*

**SB**: A pre-filled syringe has been considered a combination product in the US, but has not been treated the same in the EU. In many ways, the EU filing has been considered less burdensome to date. However, there are changes in process in the EU around drug-device combination (DDC) products. These changes and the evolving Medical Device Directive will place more rigor within the regulatory requirements for these products in the EU. Similar to the industry rollout of the FDA combination product ruling, many questions surround what information will be required of manufacturers, as well as where it should be recorded in the filing. Such changes will also include new requirements on the review and data provided by notified bodies, which may subsequently necessitate that a pharma company change their notified body and re-evaluate programs that will not be "grandfathered in." The pharmaceutical industry needs to stay apprised of and ready for these changes, as the result is still in flux as the effective date approaches in 2020.

*The forthcoming EU Medical Device Directive and regulatory changes will pose new requirements for pharma/device developments, particularly on what information and data will be required during filing. The industry needs to stay apprised of these changes and ready for 2020.*

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***HW**: Traditionally lifecycle management refers to legacy products, but with the increase in biosimilars and generics, and connected device platforms, it seems combo products developers need to start thinking about LCM at launch, or even before. What are your thoughts on this?*

**SB**: Having worked in multiple industries, my perspective is that it should never be considered that LCM refers only to legacy products. That type of thinking stems from the fact that the "sustaining engineering" portion of the lifecycle is only considered after it has become a problem in the field (i.e., not proactive thinking). LCM should be considered and integrated as early as possible in development, hands down. The word "lifecycle" itself should drive the understanding that LCM covers everything from portfolio management to sustaining engineering.

***HW**: Can you give us a snapshot of your workshop session, and what can attendees anticipate?*

**SB**: The introduction of connectivity and phone apps that are medical devices brings in an entirely new set of lifecycle management challenges for pharma. The development process is different. Software as a medical device, or embedded in connected devices, has specific regulatory requirements and compliance concerns specified in IEC 62304. Most pharma companies, phone-app development houses and IT groups in pharma have very little experience with these processes.

Product support is different. Most pharma companies are just getting used to handling medical device complaints for their auto-injector. Now they may start to dread their loaded call centers when Apple makes their next major iOS update. Post-launch strategies will inevitably have to change. Regulations will also need to determine how to handle the latest firmware update for their connected device when a security concern is brought up at BlackHat. Device development will need to evaluate if they want to make a "lifetime buy" when their connectivity chipset has been discontinued, or if the entire product line will need to be updated to keep up with the consumer electronics industry.

In our session, we'll be talking about all of these scenarios and more. In addition to presentation, attendees can expect group breakouts to dive into the problem solving strategies for pharma to adopt and adapt to the ever connected world.

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Steven will be leading an interactive preconference workshop at this summit on **Tuesday, June 19**, on:

**Integrating Connectivity into Your Devices & Your Company** (15:00 – 18:00)

Digital add-ons have become extremely popular amongst combination products developers. Recent evidence demonstrates significant ROI for connected health in pharma. This workshop will inform your decisions about integrating digital health into the pharmaceutical domain — helping you to:

- Assess the quality, lifecycle and regulatory impacts on digital health across your organization
- Recognize common execution risks and how to mitigate them
- Evaluate technology platforms and business models