Vendor Questions

Discovery questions to help determine if product design will improve patient and caregiver safety

GENERAL

- When were stakeholders included during product design?
    - What was the background (professional role, practice site, experience, etc.) of these stakeholders?

- Why was a product designed in a certain manner?
    - Especially when YOU notice best practices (ISMP, USP, regulatory standards, FDA, etc.) not incorporated

- What guidelines/standards exist in this field/product area?
    - Are there FDA or other regulatory requirements for compliance?
    - What criteria is used to differentiate "high quality" versus "low quality" products in this field?
    - How do the results/metrics shared compare with those field standards?

- For metrics or claims on the product provided by the company…
    - Are these results reproducible at your organization?
    - Does independent data support the claim?
    - Was the study design appropriate?
    - Were the claims/indication/purpose approved by the FDA?
    - Do their claims match the products approved indication/purpose (i.e., FDA purpose on 510(k) form)?

PRODUCT DESIGN PHASES

UNDERSTAND

- What research was completed and how was it conducted? How did the designer/vendor acquire this background information? Was it from a variety of hospital types (i.e., rural, health networks, teaching, etc.)?
- How did this vendor try to understand the user/customer needs?
- Who helped develop the solution to the problem trying to resolve? Who were the key players involved with product design?
- How did the vendor ensure the solution/product generated was going to resolve the original problem/need?

EXPLORE

- What was the unmet user/customer need that inspired this product?
- What was the problem this product design was trying to solve?
- What was the metric utilized that defined your failure rate? What was the failure rate discovered during testing?
- What metrics were used to measure success? How were these designed? Were any of these measures patient-oriented?
- How much testing/validation was completed for this product? What factors influenced the amount completed?
- How did they acquire information during beta testing? Who was involved with beta testing?

MATERIALIZE

- Were flaws discovered during design/development of the product?
    If yes – How were they handled? What types were seen? Why did they arise? Did they influence practice?
- How does the company stay up to date on references/materials/best practices within their field?
- How do they acquire information for product optimization? How often do they analyzing their product for refinement?
- What tests are completed to ensure a quality product was made BEFORE sending to users/customers?
- What quality assurance steps are incorporated when building the product to prevent a faulty item arriving to a customer?