Draft Language on Proposed Metrics for Pilot

September 15, 2016

Table 1.
Category: I. QS
Subcategory: B. Trending

Information to Evaluate	Evaluation Criteria	Notable feedback
Preproduction, production and postproduction information* as described by the Medical Device Innovation Consortium as it applies to product classification *abc.defg* for a *representative device*. Identify any goals established by your firm for these metrics. Describe any analysis conducted by your firm to identify increasing or decreasing trends. Describe any linkages established by your firm between the results of your preproduction, production and postproduction metrics and your firm's quality system and risk management system. The minimum reporting period is 6-months prior to the date of this notice. * Including document numbers for any references	1. Preproduction, production and postproduction information have been provided for the identified product classification for the prior 6-months. Increasing and decreasing trends have been identified. Any trends negatively impacting product and service quality are associated with actions taken by the applicant. 2. The reporting period is at least 12-months. Goals associated with preproduction, production and postproduction metrics have been established. The applicant's analysis includes an evaluation of factors that contributed to increasing and decreasing trends. 3. Tying QS trending analysis to the firm's risk management system in order to identify, control and contain emergent issues before product is released, or to promote prompt response once it is released.	• Consider a 2-tier strategy: because "meets" is merely the compliance floor. • Better to pick one device model than all models/variations of same device • Would a company that is running at 99.9% RFT but doesn't somehow link that to the Risk Management system considered worse than a company that has a 70% RFT but does? • Companies shouldn't spend resources trying to implement a system to fix things that aren't broken and if you continually have exceptional numbers on Right-First-Time, would you really need to do tier 2 and 3? • There should be a limit to how much information can be submitted and 50 pages seems adequate. You might be better served by providing a questionnaire (or an on-line firm that limits characters).

Table 2
Category: II. Device Specific Quality
Subcategory: A. Approach to Control

Factor	Information to Evaluate	Evaluation Criteria	Notable feedback
1. Risk Management	Information* on your risk management system for each identified characteristic including as it applies to product classification *abc.defg* for a *representative device*. Specifically, please provide information on your risk evaluation and risk control measures implemented to reduce overall residual risk to an acceptable level. For the identified characteristic, please identify sources of information used as an input to your risk management system, in order of significance, for both at the initial risk analysis and the ongoing post-production analysis. Please describe the extent that you have implemented all of the elements of ANSI/AAMI/ISO 14971:2007. Please indicate the extent to which your risk control measures include proactive mitigation activities such as operator error proofing or mistake proofing.	1. Risk evaluation and risk control measures show that risk has been reduced to the level the applicant determined to be acceptable. Sources of post-production analysis include, at a minimum: production records, service, returns, rework, scrap, CAPA, complaints, MDR, design changes, literature reviews, and recalls. 2. Risk analysis includes an evaluation of risk as it relates to production and manufacturing; e.g. a process. FMEA. Risk management activities are proactive to the point of including all elements of the risk management process as described in ANSI/AAMI/ISO 14971:2007; i.e. Risk Analysis, Risk Evaluation, Risk Control, Residual Risk Acceptability, Risk Management Report, and Production and Post-Production Information. 3. Sources of input to the initial risk analysis and ongoing post-production analysis include competitor products or similar devices. Risk mitigation includes operator error proofing and/or mistake proofing in manufacturing. There are efforts for continuous improvement of the device and manufacturing process. There are indications of preventive efforts to evaluate risk in a scientific manner, e.g. utilizing information from external registries and/or patient groups.	One recommendation to focus more on risk mitigation and one recommendation to focus on trending of the results of risk analysis.

	* Including document numbers for any references		
2. Control Methods	**Directly Control of Characteristic:** Information* each identified characteristic as it applies to product classification *abc.defg* for a *representative device* on how requirements associated with the feature/characteristic are directly evaluated (e.g. testing, full inspection). Also provide information on how information from risk analysis was utilized to ensure that factors that influence this method of control are appropriate for the level of risk (e.g. Gauge R&R, Calibration Planning, Test Method Validation, specific equipment controls). Please indicate where direct controls are utilized in combination with preventive controls (see below) **Preventive Control of Characteristic:** Information* each identified characteristic as it applies to product classification *abc.defg* for a *representative device* on the *critical limits* and *operating limits*; how you derived these limits (e.g. risk analysis, Design of Experiments, etc.); and, what control are in place to prevent routine deviations from critical limits. Where statistical methods are utilized, please provide information according to Table 3 below.	**Directly Control of Characteristic:** 1. Identification of method utilized to ensure that requirements are met for each identified characteristic. Information on how risk analysis has been used to ensure the appropriateness of this method. 2. Direct controls are utilized in combination with preventive controls (see below). 3. The method used to ensure that requirements are met includes operator error proofing and/or automated controls to ensure that commonly occurring problems (e.g. use of obsolete SOPs, use of equipment with calibration, inadequate operator training, and/or component mixup) are prevented. **Preventive Control of Characteristic:** 1. Identification of critical limits and operating limits indicating that operating within these limits prevents, eliminates or reduce to an acceptable level of occurrence of a hazard. Statistical methods are based on an analysis of risk. 2. The preventive control was developed based on process validation activities ensuring that key input variables result in on-target performance for the preventive control; and, that the preventive control is capable under actual operating conditions. 3. The method used to ensure that requirements are met includes operator error proofing and/or automated controls to ensure that commonly occurring problems (e.g. out of date SOP, out of date equipment calibration, untrained operator, and/or incorrect component) are prevented.	One recommendation to segregate the information submitted by specific control types (environmental, production, testing,…)

	Characteristic Outsourced: Information* each identified characteristic on what controls you require for suppliers of product(s) or service(s) that impact the identified characteristic; information on how controls for these suppliers are based on product or service risk; and how the applicant has evaluated the supplier's ability to fulfill requirements. ***** Including document numbers for any references	**Characteristic Outsourced:** 1. Controls are identified for suppliers based on an evaluation of risk of the product and the capability of the supplier to fulfill requirements. 2. Information indicating that the applicant has established controls intended to prevent product problems. The applicants approach includes controls that extend to second or further-tier suppliers. 3. The supplier controls defined by the applicant include activities related to more rapid supplier communication, operator error proofing and/or automated controls to ensure that commonly occurring problems (e.g. out of date SOP, out of date equipment calibration, untrained operator, and/or incorrect component) are prevented.	
4. Monitoring	Information* each identified characteristic as it applies to product classification *abc.defg* for a *representative device* specific to the identified characteristic and control identified in Table 2 above (direct and preventive controls) showing how the applicant collects data on the control to ensure that it is suitable over time. Information should define the frequency of data collection and what method(s), including statistical methods, the applicant uses to ensure the suitability of the control. **Characteristic Outsourced:** Information* each identified characteristic on what information the applicant collects to ensure the suitability over time of a supplier of product(s) or service(s) that impact the identified characteristic. ***** Including document numbers for any	1. Characteristics with preventive controls are routinely monitored and evaluated to ensure that characteristics stay within critical and operating limits. Where sampling is utilized, the Lot Tolerence Percent Defective is less than the allowable defect level derived from risk analysis. 2. Monitoring of controls utilizes methods such as statistical process control (SPC) capable of detecting product or process problems before defects occur and that a state of statistical control is maintained. 3. Monitoring of characteristics is performed relative to key process variables allowing not only evaluation of the control but evaluation of other factors that impact the characteristic or identification of new factors. **Characteristic Outsourced:** • Approach to monitoring includes information from controls extended to suppliers and their ability to fulfill requirements beyond cost and schedule, for example, supplier incoming quality.	Received a recommendation to make Outsourcing a separate factor altogether.

	references		

Table 3: Information Needed for Different Statistical Approaches	
Statistical Method:	What to Submit Information from statistics SOP on how statistical levels tie to risk assessments, plus:
Tolerence Intervals	Confidence and Reliability Levels
Acceptance Sampling	Lot sizes, AQL and LTPD
CpK / PpK	CpK or PPk and 95% confidence interval for CpK or PPk respectively
Other	Name of the statistical method, statistical results and statistical parameters that impact the interpretation of the result

Table 4
Category: II. Device Specific Quality
Subcategory: B. Trending

Factor	Information to Evaluate	Evaluation Criteria	Notable feedback
	Information* each identified characteristic as it applies to product classification *abc.defg* for a *representative device* specific to the identified characteristic and control identified in Table 2 above (direct and preventive controls) showing how the applicant collects data on the control to ensure that it is suitable over time. Information should define the frequency of data collection and what method(s), including statistical methods, the applicant uses to ensure the suitability of the control. **Characteristic Outsourced:** Information* each identified characteristic on what information the applicant collects to ensure the suitability over time of a supplier of product(s) or service(s) that impact the identified characteristic. ***** Including document numbers for any references	1. Trending of controlled characteristics is routinely evaluated for suitability of the control to ensure that characteristics have stayed within critical and operating limits. 2. Where trending has shown deviating patterns, corrective actions have been taken to return a deviating trend to a controlled state. 3. Trending analysis can be conclusively demonstrated to lead to preventive actions, and that product quality is maintained during a preventive actions. **Characteristic Outsourced:** 1. Trending of controlled characteristics is routinely evaluated for suitability of the control to ensure that characteristics have stayed within critical and operating limits. 2. Where trending has shown deviating patterns, corrective actions have been taken to return a deviating trend to a controlled state. 3. Trending analysis can be conclusively demonstrated to lead to preventive actions, and that product quality is maintained during a preventive actions.	Monitoring is in the present tense; trending is in the past tense. As we move from Level 1, to 2 and 3, the degree of prevention increases.