Workshop: Data Integrity Risk Management

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Process Step	Managed Data	Data Integrity Failure	Consequences (Product Quality and Process Safety, Patients Safety)	Root Cause	Risk Level (high / medium / low)	CAPA (Risk Reduction or Control Measures)
110 Get Menu Card	Article No	**A** (not or incorrect attributable)	difficult to change menu card in the future	no (documented) ownership of menu card, no signature of printing company	low	n/a
		L (not enough legible)	difficult to read menu => misunderstanding => wrong order	poor print quality, poor education of menu's editor	medium	version control menu card, approval procedure menu card
		C (not sufficient contemporaneous)	wrong pricing => customer has to pay higher price than expected	no update procedure	medium	document control printed menu cards (release and recall), review and update procedure
		O (not original / reliable)				
		A (not sufficient accurate)				

- Split into small Teams
- Workshop Objectives
  - Risk Identification in complete Process
  - By View through ALCOA-Glasses
  - Evaluation of Impact and Root Cause
  - Definition of Risk Reduction and Control Measures
  - **Time Objective: 60 min**
  - Discussion and Comparison of Results: 15 min