General

QUALITY RELATED ACRONYMS

ISO International Organization for Standardization CAPA Corrective Action / Preventive Action

SOP Standard Operating Procedure MRB Material Review Board

KPI Key Process Indicator

CTQ Critical – to -Quality CTF Critical –to-Function

OOS Out-of-Specification OOT Out-of-Tolerance

CoC Certificate of Conformance (Certificate of Compliance) CoA Certificate of Analysis

FDA (Medical device 21CFR 820, Pharmaceutical 21CFR210/211)

cGMP current Good Manufacturing Practices cGLP current Good Laboratory Practices CGCP current Good Clinical Practices

cGxP current Good (Mfg, Lab or Clin) Practices