

Annex 1 – National QP Information

EU Member States

Austria[★]

Latest update November 2020

Official Authority certifying QPs Address (Web Address)	Bundesamt für Sicherheit im Gesundheitswesen (BASG) – AGES MEA Traisengasse 5 A-1220 Wien Austria www.ages.at
Name	Sachkundige Person
Requirements for becoming a QP	• Pharmacists - other possible professions: Medical doctors, chemists or biologists • Additional training for non-Pharmacists can be obtained by University course "Pharmazeutisches Qualitätsmanagement" • Must provide evidence for experience • Head of QC ("Kontrolllaborleiter") or Head of Production ("Herstellungsleiter") may act as Sachkundige Person • Defined education and experience required for Head of QC and Head of Production
QP Functional Area Requirements / Specifics	In addition to EU-requirements, AMBO 2009 requires QP to approve Validation Master Plan, "Herstellungsvorschrift", Product Quality Review, Rework/Reprocessing
Interest Groups	AQPA /Austrian QP Association www.austria-qp.at
Applying for QP confirmation	https://www.basg.gv.at/inspektionen/formulare/gm_pgdg/ FI220 Antrag auf Ausstellung einer Bestätigung Sachkundige Person

[★] The summarised information represents current knowledge and may be subject to change.