

Standard Operating Procedure

Title: Authorised Persons

Department	Quality Management	Document no	QMS-070
Prepared by:		Date:	Supersedes:
Checked by:		Date:	Date Issued:
Approved by:		Date:	Review Date:

Document Owner

Quality Assurance Manager

Affected Parties

Quality Assurance Management

Purpose

The purpose of this document is to describe the accreditation, accountabilities and responsibilities of an Authorised Person. (AP)

Definition

AP	Authorised Person
Bulk production batch	A batch of product, of a size described in the Marketing Authorisation, either ready for assembly into final containers or in individual containers ready for assembly into final packs.
Finished product batch	A batch of product in its final pack for release to the market

Related Documents

QMS-035	Deviation Report System
QMS-090	Evaluation of Batch Documentation and Release for Sale

EHS Statement

There is no EHS implication.

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1. Procedure

- 1.1. The principles for certification by an authorised person and batch release outlined in the Code of Good Manufacturing Practice of regulatory agencies will apply.
- 1.2. The Authorised Person who is accredited to release products for sale (for some regulated industries) to designated markets is recognised by the Quality Assurance Manager as having:

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Version #	Revision History
QMS-070	New