MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

# Guidelines on the Regulation of Therapeutic Products in New Zealand

## Manufacture of medicines

Edition: 5.4
November 2024

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# Contents

# List of abbreviations

| Abbreviation or term | Definition/Explanation |
|---|---|
| CMN | changed medicine notification |
| CPP | certification of pharmaceutical product |
| CRPN | changed related product notification |
| DNA | deoxyribonucleic acid |
| EIR | Establishment Inspection Report |
| EU | European Union |
| FDA | Food and Drug Administration (United States of America) |
| GMP | Good Manufacturing Practice |
| ISO | International Organization for Standardization |
| NZ | New Zealand |
| NMA | new medicine application |
| NRPA | new related product application |
| OTC | Over-the-counter medicine |
| PIC | Pharmaceutical Inspection Convention |
| PIC Scheme | Pharmaceutical Inspection Co-operation Scheme |
| PIC/S | PIC and PIC Scheme operating together in parallel |
| TGA | Therapeutic Goods Administration (Australia) |
| USA | United States of America |
| WHO | World Health Organization |

# 1. When is GMP documentation required?

Medsafe requires evidence of compliance with Good Manufacturing Practice (GMP) for sites used to manufacture and pack medicines. This evidence is required for medicines in New Zealand whether or not they are considered medicines in the country of origin.

Table 1 lists the sites for which GMP certification or equivalent documentary evidence should be provided.

**Table 1: Medsafe requirements for GMP evidence**

| **Manufacturing** | **Sites requiring GMP certification or equivalent documentary evidence** |
|---|---|
| Finished products | • Sites specified in a new medicine application (NMA) or changed medicine notification (CMN) (excluding master cell banks)<br>• Manufacturers of the finished product (including manufacturers of intermediate products)<br>• Sterilisers sites (finished product and components used in aseptic fill)<br>• Packers of the finished product<br>• Sites where products are over-labelled. |
| Related products | • New related product applications (NRPAs) and changed related product notification (CRPNs) for products taken internally (eg, throat lozenges, and vitamin and mineral tablets). |
| Active pharmaceutical ingredients | • Manufacturers of active pharmaceutical ingredients that are prescription medicines |

Medsafe does not require evidence of GMP for related product for external use. However, Medsafe requires evidence to show the manufacturer complies with an internationally recognised quality system (eg, ISO accreditation).

For active pharmaceutical ingredients, Medsafe requires evidence that the material is manufactured consistently and produced with acceptable quality.

## Manufacturing and packing

A manufacturing site for a finished product is any site which contributes to a manufacturing operation which converts raw materials to a finished dose form (this includes sterilising sites). A packing site means any site which contributes to a packing operation which places the final dose form into its labelled primary or secondary container.

### New Zealand

Manufacturers and/or packers with premises in New Zealand must hold an appropriate current licence to manufacture and/or pack medicines. The licence must have been issued for the site for the manufacture and/or packaging of the type of product or packaging operation before manufacture or packaging of the product for distribution can commence. Provided

they hold such current licences, certification need not be provided with each application or notification.

**Overseas**

For overseas manufacturers and packers, Medsafe requires that current certification be included with each NMA or CMN which relates to a change of site, even if the site already supplies product to New Zealand and certification has been supplied previously with an earlier application or notification. This reduces delays associated with locating other files, and because it is desirable for the certification to be product-specific and up-to-date.

If acceptable evidence of GMP compliance is not available, an audit of the site by Medsafe auditors can be arranged at the applicant's request and expense.

Medsafe also requires sponsors to continue supplying evidence of current GMP compliance on an ongoing basis, to ensure registered products continue to meet consented requirements. Updated evidence should be submitted, to GMP@health.govt.nz, as soon as it becomes available for each site involved in the manufacturing activities listed above. There is no associated fee.

# 2. Recognised documentation

Medsafe recognises any GMP certification document issued by a recognised authority that confirms GMP compliance (refer to section 5 for the list of recognised authorities). Acceptable evidence normally consists of copies of appropriate certificates, manufacturing licences or reports.

Table 2 below provides document requirements and Tables 3 and 4 provide examples of acceptable and unacceptable evidence of GMP certification.

**Table 2: Requirements for GMP certification documents**

| Requirement | Details |
|---|---|
| Content of the certificate, licence or report | • Street address of the site concerned<br>• Reference to the product or active ingredient, or product class<br>• Reference to GMP acceptability and/or to a GMP audit<br>• Name of the issuing authority<br>• Date and signature, unless the certificate is current and published on the EudraGMP database or is a TGA GMP clearance.<br>• Date of expiry of the certification or licence, where applicable (FDA EIR documents and TGA licences do not have expiry dates). |
| Age of the certificate, licence or report | • No more than 3 years old when the NMA or CMN is submitted<br>• Must be current at the time of approval of the new or changed product for distribution in New Zealand. |
| Language | • English<br>• If the original documentation was not in English, then copies of both the original documents and a certified English translation must be submitted. |

**Table 3: Examples of acceptable evidence of GMP certification**

The following examples are not an exhaustive list and although acceptable, in some instances do not meet all of the requirements of table 2.

| Acceptable evidence | Notes |
|---|---|
| Licence to manufacture issued by a recognised authority | The licence is issued only where the site is inspected and regularly re-inspected for GMP compliance. |
| Current registration and entry of the site in the Australian Register of Licenced Manufacturers | For the product, product class or process concerned. |

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|---|---|
| Certification of pharmaceutical product (CPP) issued under the WHO scheme by a recognised authority which certifies the quality of pharmaceuticals moving in international commerce | CPP is only acceptable if it refers to a GMP audit/inspection conducted by a recognised issuing authority. CPP is not applicable for an active pharmaceutical manufacturer. In cases where the CPP represents regulatory decisions accepted under EU recognition arrangements, and does not reflect a GMP assessment by the recognised regulator, the CPP is unacceptable. The CPP is valid only for the medicinal products for which the CPP has been issued. |
| Canadian Drug Plant Inspection Rating Report | |
| Letter or file note from a recognised authority confirming GMP compliance | For example, an extract from FDA files obtained by the manufacturer under the Freedom of Information Act (USA). The extract usually states that an audit occurred on the given date and gives the outcome of the audit. This should include evidence of the scope of the audit. In some instances unredacted reports may be sent directly to Medsafe, in confidence.<br>The extract must meet at the requirements of table 2. |
| Certificate issued by the TGA | TGA has confirmed (eg, with the FDA) that GMP compliance at the particular site is satisfactory. |
| GMP facilities awaiting an inspection by the FDA | Where a site has current and ongoing approval from the FDA, Medsafe will accept the most recent certificate with a letter from the facility confirming that they are awaiting an FDA inspection. Medsafe has access to the FDA's electronic GMP database and will verify the GMP status of manufacturing facility. |

**Table 4: Examples of unacceptable evidence of GMP certification**

| **Unacceptable evidence** | **Notes** |
|---|---|
| Licence to manufacture that was not issued by a recognised authority | |
| Certification issued by a pharmaceutical company | Not acceptable, even if the company certifying is not the same as the manufacturer or packer. |
| Annual Registration of Drug Establishment (USA) | This document is not indicative of GMP compliance. |

# 3. Classes of medicine

Medsafe prefers product-specific certification such as certification in the WHO format or a manufacturing or product licence listing the product.

If product-specific certification cannot be obtained, the certification must relate to a medicine or medicines of the same class(es) (see Table 5 below) as the one which is the subject of the application or notification. A medicine may belong to more than one class. In such cases, the certification should be for a product belonging to the same classes.

**Table 5: Medicine classes**

| | |
|---|---|
| I | Medicines containing penicillin |
| II | Medicines containing cephalosporin |
| III | Vaccines or sera |
| IV | Sterile medicines |
| V | Hormones and steroids |
| VI | Microdose preparations (other than vitamins), i.e., containing 5 mg or less per unit dose |
| VII | Antineoplastic agents and immunosuppressant agents (other than steroids) |
| VIII | Solid dose forms |
| IX | Recombinant DNA medicines |
| X | Metered dose aerosol preparations |
| XI | Liquids, creams, ointments |
| XII | Non-metered dose aerosols |
| XIII | Powders |
| XIV | Wound dressings |
| XV | Transdermal patches |

# 4. Sites that manufacture active pharmaceutical ingredients

### Active pharmaceutical ingredients for prescription medicines

Medsafe requires evidence of GMP for all sites that manufacture active pharmaceutical ingredients for prescription medicines. Such evidence should be included with each application or notification which relates to a change of site.

Applications and notifications must include the name and address of the actual site of manufacture. Applicants should ensure that there is no confusion between sites of manufacture and addresses of company head offices or brokers. Any documentary evidence of GMP must refer to the actual site of manufacture.

Where GMP certificates specifically list individual substances, it does not need to include the substance relating to the Medsafe application, unless the site manufactures antibiotics or highly sensitizing agents. In these instances, a declaration is required in the form of a letter from manufacturing site, that the substance is manufactured under the same quality system, and in the same facility using a similar manufacturing process (for example, chemical synthesis) as those substances listed in the GMP certificate or inspection report (for example EIR issued by the USFDA). The declaration should be signed by the Head of Quality (or similar) or Qualified Person.

GMP evidence is not required for API manufacturing sites included in applications submitted via the abbreviated route and based on European approval, where European acceptance of the API manufacturing site was based on a QPP. Refer to outcome of consultation published on 24 April 2013 in this link https://www.medsafe.govt.nz/hot/Consultation/OutcomeGMPReviews.asp.

### Active pharmaceutical ingredients for OTC medicines and related products

Medsafe requires evidence that the active pharmaceutical ingredients used for OTC medicines and related products is manufactured consistently and produced with acceptable quality. Table 6 lists documents that are acceptable as evidence for manufacturers of active pharmaceutical ingredients used in OTC medicines and related products.

**Table 6: Acceptable evidence for manufacturers of active pharmaceutical ingredients for OTC medicines and related products**

| Acceptable evidence | Notes |
|---|---|
| A GMP certificate or inspection report issued by a recognised authority<br><br>***Note:*** *A GMP certificate alone is not acceptable as a substitute for a Drug Master File, Certificate of Suitability or batch analytical data where these are normally required.* | Not all authorities issue certification for sites manufacturing active pharmaceutical ingredients. |

| | |
|---|---|
| A Drug Master File or equivalent data | Submitted as part of the dossier for a new chemical entity or new biological entity medicine. |
| European Pharmacopeial "Certificate of Suitability" | For an active pharmaceutical ingredient controlled according to the European Pharmacopoeia. |
| Batch analytical data | Demonstrating consistent quality of the active pharmaceutical ingredients produced (accepted as adequate evidence only for OTC and related products). |

# 5. Recognised authorities

Medsafe recognises GMP certification issued by the authorities listed in Table 7 below. These authorities include the competent authorities in the European Union accepted under the EU-NZ Mutual Recognition Agreement, certain member authorities of the PIC and/or PIC/S organisations, and other authorities where Medsafe has information that GMP assessment systems that are compatible with New Zealand expectations exist. The inclusion of the listed European Union competent authorities is a consequence of the Mutual Recognition Agreement in Relation to Conformity Assessment that became effective between New Zealand and the European Community on 1 January 1999. Medsafe added further authorities to this list in August 2023 after completing an assessment of the authorities' systems.

Omission of an authority from the list generally indicates that Medsafe has not assessed that authority's systems and should not be construed in any way as an adverse reflection on the competence of the authority itself.

**Table 7: Authorities recognised by Medsafe**

| Logo (for information only) | Recognised Authority (alphabetical by country) |
|---|---|
| Australian Government<br>Department of Health<br>Therapeutic Goods Administration | **AUSTRALIA**<br>Therapeutic Goods Administration<br>Website: http://www.tga.gov.au/ |
| AGES | **AUSTRIA**<br>Austrian Agency for Health and Food Safety<br>*Österreichische Agentur für Gesundheit und Ernährungs-sicherheit* (AGES)<br>Website: https://www.ages.at/en |
| famhp<br>federal agency for medicines and health products | **BELGIUM**<br>Federal Agency for Medicines and Health Products<br>*Agence Fédérale des Médicaments et des Produits de Santé* (AFMPS)<br>*Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten* (FAGG)<br>Website: https://www.fagg-afmps.be/en |
| | **BULGARIA**<br>Bulgarian Drug Agency (BDA)<br>*ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА*<br>Website: https://www.bda.bg/en/ |

| Logo (for information only) | Recognised Authority (alphabetical by country) |
|---|---|
| Health Canada Santé Canada | **CANADA**<br>Health Canada<br>*Regulatory Operations and Regions Branch (RORB)*<br>*Direction générale des opérations réglementaires et des régions (DGORR)*<br>Website: https://www.canada.ca/en/health-canada.html |
| HALMED Agency for Medicinal Products and Medical Devices of Croatia | **CROATIA** Agency for Medicinal Products and Medical Devices of Croatia<br>*Agencija za lijekove i medicinske proizvode (HALMED)*<br>Website: https://www.halmed.hr/en/ |
| | **CYPRUS**<br>Pharmaceutical Services (CyPHS)<br>Website: https://koef.org.cy/pharmaceutical-services/ |
| SÚKL State Institute for Drug | **CZECH REPUBLIC**<br>State Institute for Drug Control<br>*Státní Ústav pro Kontrolu Léčiv (SÚKL)*<br>Website: http://www.sukl.eu/index.php?lang=2 |
| LÆGEMIDDELSTYRELSEN DANISH MEDICINES AGENCY | **DENMARK**<br>Danish Medicines Agency (DKMA)<br>Website: http://laegemiddelstyrelsen.dk/en/ |
| Republic of Estonia Agency of Medicines | **ESTONIA**<br>State Agency of Medicines *(SAM)*<br>Website: https://ravimiamet.ee/en |
| fimea Finnish Medicines Agency | **FINLAND**<br>Finnish Medicines Agency (FIMEA)<br>Website: http://www.fimea.fi/web/en |

| Logo (for information only) | Recognised Authority (alphabetical by country) |
|---|---|
| | **FRANCE**<br>French National Agency for Medicines and Health Products Safety<br>*Agence nationale de sécurité du médicament et des produits de santé (ANSM)*<br>Website: http://ansm.sante.fr/ |
| | **GERMANY***<br>Federal Ministry of Health<br>Website: http://www.bundesgesundheitsministerium.de/<br>**AND**<br>Central Authority of the Lander for Health Protection with regard to Medicinal Products and Medical Devices<br>*Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)*<br>Website: https://www.zlg.de/en/<br>* The PIC/S website contains the statement *"The German Ministry of Health (BMG) and the German Authority of the Lander (ZLG) count as one PIC/S participating Authority."* Therefore both authorities are recognised by Medsafe. |
| | **GERMANY (IMMUNOLOGICALS)**<br>Paul-Ehrlich-Institut – Federal Institute for Vaccines and Biomedicines<br>Website: https://www.pei.de/EN/home/home-node.html |
| | **GERMANY REGIONAL STATE AUTHORITIES LISTED BELOW ARE ALSO ACCEPTABLE GERMAN AUTHORITIES***<br>* The PIC/S website states *"All German Medicinal Authorities, which are listed on the ZLG website, are considered as PIC/S Participating Authorities and are represented in PIC/S by ZLG."* The list of authorities below has been provided to Medsafe by ZLG. Current authorities can be verified at https://www.zlg.de/arzneimittel/deutschland/laenderbehoerden.html (website is in German only)<br>**BADEN-WÜERTTEMBERG**<br>*Regierungspräsidium Tübingen (Referat 25)*<br>*Leitstelle Arzneimittelueberwachung Baden-Wuerttemberg; Sachgebiet Pharmazeutische Angelegenheiten*<br>*Sachgebiet 3 Arzneimittel-, Apotheken- und Medizinproduktewesen Pharmazeutische Angelegenheiten*<br>*Regierungspräsidium Freiburg (Referat 25)*<br>*Regierungspräsidium Karlsruhe (Referat 25)*<br>*Regierungspräsidium Stuttgart (Referat 25)* |

| Logo (for information only) | Recognised Authority (alphabetical by country) |
|---|---|
| | **BAYERN**<br>*Regierung von Oberbayern Sachgebiet 53.2 – Pharmazie*<br>*Regierung von Oberfranken*<br>**BERLIN**<br>*Landesamt für Gesundheit und Soziales Berlin (LAGeSo), Referat I F 3 Arzneimittelwesen (Pharmazeutisches Inspektorat)*<br>**BRANDENBURG**<br>*Landesamt für Umwelt, Gesundheit und Verbraucherschutz*<br>*Referat G4 Apotheken, Arzneimittel Medizinprodukte*<br>**BREMEN**<br>*Senator für Gesundheit Referat 44 Pharmazie, Toxikologie, Gentetechnik*<br>**HAMBURG**<br>*Behörde für Gesundheit und Verbraucherschutz*<br>**HESSEN**<br>*Regierungspräsidium Darmstadt Dezernat II 23.1 und 23.2*<br>**MECKLENBURG-VORPOMMERN**<br>*Arzneimittelüberwachungs- und –prüfstelle Mecklenburg-Vorpommern*<br>*LALLF Rostock*<br>**NIEDERSACHSEN**<br>*Staatliches Gewerbeaufsichtsamt Braunschweig*<br>*Staatliches Gewerbeaufsichtsamt Hannover*<br>*Staatliches Gewerbeaufsichtsamt Lüneburg*<br>*Staatliches Gewerbeaufsichtsamt Oldenburg*<br>*Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit* |
| | **NORDRHEIN-WESTFALEN**<br>*Bezirksregierung Arnsberg*<br>*Bezirksregierung Detmold*<br>*Bezirksregierung Düsseldorf*<br>*Bezirksregierung Köln*<br>*Bezirksregierung Münster*<br>*Gesundsheitamt der Stadt* |

| Logo (for information only) | Recognised Authority (alphabetical by country) |
|---|---|
| | *Landesamt für Natur, Umwelt und Verbraucherschutz*<br><br>**RHEINLAND-PFALZ**<br><br>*Landesamt für Soziales, Jugend und Versorgung*<br><br>*Kreisverwaltung Mainz-Bingen*<br><br>**SAARLAND**<br><br>*Ministerium für Soziales, Gesundheit, Frauen und Familie Referat E3 / Referat E4*<br><br>**SACHSEN**<br><br>*Landesdirektion Sachsen Referat 24L Pharmazie, GMP-Inspektorat*<br><br>**SACHSEN-ANHALT**<br><br>*Landesverwaltungsamt Sachsen-Anhalt Referat 604 Gesundheitswesen, Pharmazie*<br><br>**SCHLESWIG-HOLSTEIN**<br><br>*Landesamt für soziale Dienste des Landes Schleswig-Holstein*<br><br>**THÜRINGEN**<br><br>*Thüringer Landesamt für Verbraucherschutz* |
| Εθνικός Οργανισμός Φαρμάκων National Organization for Medicines | **GREECE**<br><br>National Organisation for Medicines<br><br>*Εθνικός Οργανισμός Φαρμάκων (EOF)*<br><br>Website: http://www.eof.gr/web/guest |
| NNGYK NATIONAL CENTER FOR PUBLIC HEALTH AND PHARMACY | **HUNGARY**<br><br>National Center for Public Health and Pharmacy (NCPHP)<br><br>Website: https://nnk.gov.hu/ |
| Lyfjastofnun Icelandic Medicines Agency | **ICELAND**<br><br>Icelandic Medicines Agency (IMA)<br><br>Website: https://www.ima.is/ |
| HPRA An tÚdarás Rialála Táirgí Sláinte Health Products Regulatory Authority | **IRELAND**<br><br>Health Products Regulatory Authority (HPRA)<br><br>Website: https://www.hpra.ie/ |

| Logo (for information only) | Recognised Authority (alphabetical by country) |
|---|---|
| | **ITALY**<br>Italian Medicines Agency<br>*Agenzia Italiana del Farmaco (AIFA)*<br>Website: https://www.aifa.gov.it/en/l-agenzia |
| | **JAPAN**<br>Ministry of Health, Labour and Welfare (MHLW)<br>Website: http://www.mhlw.go.jp/english/<br><br>Pharmaceuticals and Medical Devices Agency (PMDA)<br>Website: http://www.pmda.go.jp/english/ |
| | **LATVIA**<br>State Agency of Medicines<br>*Zāļu valsts aģentūra (ZVA)*<br>Website: https://www.zva.gov.lv/en |
| | **LIECHTENSTEIN**<br>Office of Healthcare<br>*Amt für Gesundheit (AG)*<br>Website: http://www.llv.li/#/1908/amt-fur-gesundheit |
| | **LITHUANIA**<br>State Medicines Control Agency *(SMCA)*<br>Website: https://sam.lrv.lt/en/ |
| | **LUXEMBOURG***<br>Ministry of Health<br>*Direction de la Santé Villa Louvigny Division de la Pharmacie et des Medicaments*<br>Website: https://sante.public.lu/fr/index.php<br>*Note: Luxembourg Ministry of Health is not a PIC/S member. However, is recognised under the New Zealand–European Community Mutual Recognition Agreement of Conformity Assessment, Certificates and Markings (L 229/62, 17.8.98) |

| Logo (for information only) | Recognised Authority (alphabetical by country) |
|---|---|
| MALTA MEDICINES AUTHORITY | **MALTA**<br>Malta Medicines Authority (MAM)<br>Website: http://www.medicinesauthority.gov.mt/home?l=1 |
| Inspectie Gezondheidszorg en Jeugd<br>*Ministerie van Volksgezondheid, Welzijn en Sport* | **NETHERLANDS**<br>Health Care Inspectorate<br>*Inspectie voor de Gezondheidszorg (IGZ)*<br>Website: https://www.igz.nl/english/ |
| Statens legemiddelverk<br>Norwegian Medicines Agency | **NORWAY**<br>Norwegian Medicines Agency (NOMA)<br>Website: https://legemiddelverket.no/english |
| Chief Pharmaceutical Inspectorate | **POLAND**<br>Chief Pharmaceutical Inspectorate<br>Website: https://www.gif.gov.pl/en |
| Infarmed<br>Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. | **PORTUGAL**<br>National Authority of Medicines and Health Products,<br>*Autoridade Nacional do Medicamento e Produtos de Saúde I.P. (INFARMED)*<br>Website: http://www.infarmed.pt/web/infarmed-en/ |
| National Agency for Medicines and Medical Devices of Romania | **ROMANIA**<br>National Agency for Medicines and Medical Devices (NAMMD)<br>Website: https://www.anm.ro/en/ |
| HSA Health Sciences Authority | **SINGAPORE**<br>Health Sciences Authority (HSA)<br>Website: https://www.hsa.gov.sg/ |
| SÚKL<br>ŠTÁTNY ÚSTAV PRE KONTROLU LIEČIV | **SLOVAK REPUBLIC**<br>State Institute for Drug Control (SIDC)<br>Website: http://www.sukl.sk/ |

| Logo (for information only) | Recognised Authority (alphabetical by country) |
|---|---|
| | **SLOVENIA**<br>Agency for Medicinal Products and Medical Devices<br>*Javna agencija Republike Slovenije za zdravila in medicinske pripomočke* (JAZMP)<br>Website: https://www.jazmp.si/en/ |
| | **SPAIN***<br>Spanish Agency of Medicinal Products and Medical Devices<br>*Agencia Española del Medicamento y Productos Sanitarios* (AEMPS)<br>*Subdirección General de Inspección y Controlo de Medicamentos*<br>*Division de Inspección y Control Farmaceútico*<br>Website: https://www.aemps.gob.es/informa-en/<br>**SPANISH REGIONAL STATE AUTHORITIES LISTED BELOW ARE ALSO ACCEPTABLE SPANISH AUTHORITIES ***<br>* The PIC/S website states *"The competence for GMP/GDP inspections in Spain is shared between the central authority, Spanish Agency for Medicines and Medicinal Devices (AEMPS) and the Spanish regional authorities, which count as one PIC/S Participating Authority. All Spanish Medicinal Authorities which are listed on the AEMPS website are considered as PIC/S Participating Authorities and are represented in PIC/S by the AEMPS."*<br>**ARAGON**<br>*Departamento de Sanidad, Dirección General de Planificación y Aseguramiento* |
| | **ISLAS BALEARES**<br>*Dirección General de Planificación, Evaluación y Farmacia. Conselleria de Salud* |
| | **CANARIAS**<br>*Servicio Canario de la Salud. Servicio de ordenación farmacéutica* |
| | **CASTILLA Y LEON**<br>*Consejería de Sanidad. Junta de Castilla y León, Dirección General de Salud Pública. Servicio de Control y Evaluación de Centros y Actividades Sanitarias* |

| Logo (for information only) | Recognised Authority (alphabetical by country) |
|---|---|
| | **CATALUNA**<br>*Generalitat de Catalunya. Departament de Salut. Dirección General de Ordenación y Regulación*<br>*Sanitarios. Subdirección General de Farmacia y Productos Sanitarias. Servicio de Control Farmacéutico y Productos Sanitarios* |
| | **GALICIA**<br>*Consellería de Sanidade. Xunta de Galicia. Servizo Galego de Saúde. Servizo de Inspección Farmacéutica*<br>*Subdirección xeral de Inspección, Auditoría e Acreditación de Servizos Sanitarios. Secretaría Xeral Técnica* |
| | **REGION DE MURCIA**<br>*Consejería de Sanidad, Dirección General de Planificación, Ordenación Sanitaria y Farmacéutica e Investigación.*<br>*Servicio de Ordenación y Atención Farmacéutica*<br>**COMUNIDAD FORAL DE NAVARRA**<br>*Departamento de Salud. Gobierno de Navarra. Sección de Inspección Farmacéutica*<br>**COMUNIDAD VALENCIANA**<br>*Conselleria de Sanidad Universal y Salud Pública. Dirección General de Farmacia y Productos*<br>*Sanitarios. Servicio de Ordenación, Control y Vigilancia de Productos Farmacéuticos* |
| LÄKEMEDELSVERKET<br>MEDICAL PRODUCTS AGENCY | **SWEDEN**<br>Medical Products Agency (MPA)<br>Website: https://lakemedelsverket.se/english/ |
| swissmedic<br>Swiss Agency for Therapeutic Products | **SWITZERLAND**<br>Swiss Agency for Therapeutic Products (Swissmedic)<br>Website: https://www.swissmedic.ch/?lang=en |

| Logo (for information only) | Recognised Authority (alphabetical by country) |
|---|---|
| Medicines & Healthcare products Regulatory Agency | **UNITED KINGDOM**<br>Medicines and Healthcare Products Regulatory Agency (MHRA)<br>Website: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency |
| FDA U.S. FOOD & DRUG ADMINISTRATION | **UNITED STATES OF AMERICA**<br>Food and Drug Administration (US FDA)<br>Website: https://www.fda.gov/ |

# Document History

| Revision Date | Revision Number | Summary of changes |
|---|---|---|
| October 2014 | Draft | Published version |
| September 2018 | 1.0 | Information in Part 4, section 1.5 of the Guideline, updates to include Malta, Poland and Catalonia.<br>Regulators' logo included and to include websites for each regulator. |
| February 2022 | 2.0 | Added requirement for GMP for API that are prescription medicines.<br>Added requirement for ongoing evidence of current GMP compliance to be provided.<br>Updated logos for Romania, and Switzerland<br>Updated websites for Canada, Hungary, Italy, Luxembourg, Romania, Singapore and Spain.<br>Removed reference to Part 5 of NZRGM. |
| 16 May 2022 | 3.0 | Removed "United Kingdom Product Licence or Product Licence Variation" as acceptable evidence of GMP in section 1.2 as this statement had been carried over in error. |
| 27 May 2022 | 4.0 | Addition of clarification around the requirement for CPP as acceptable evidence of GMP in section 1.2. |
| 16 August 2023 | 5.0 | Addition of the competent authorities of Bulgaria, Croatia, Cyprus, Estonia, Lativa, Lithuania, Slovenia to the list of recognised authorities.<br>Clarification on the examples of acceptable evidence of GMP provided by manufacturing site audited by the USFDA and also certificate published in the EUDRA database.<br>Removal to reference of 'Part 4' in the document title.<br>Grammatical and formatting changes throughout the document. |

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| 17 August 2023 | 5.1 | Minor updates to tables 2 and 3 to clarify requirements. No substantive change to meaning, or current practice. |
| 13 Sept 2023 | 5.2 | Updates to section 4 to clarify on the requirement for evidence of GMP for API site.<br>Updates to section 4 to include outcome of 2013 consultation on the proposed changes to GMP evidence required for API site. |
| December 2023 | 5.3 | Added clarifying statement '*unless the site manufactures antibiotics or highly sensitising agents*' to the sentence '*Where GMP certificates specifically list individual substances, it does not need to include the substance relating to the Medsafe application*' in section 4 paragraph 3. |
| November 2024 | 5.4 | Update the logo and the name of the recognised authority of Hungary from *National Institute of Pharmacy and Nutrition (NIPN)* to *National Center for Public Health and Pharmacy (NCPHP)* |