



IFPMA *Questions & Answers*

US Certificate of Pharmaceutical Product

Questions and Answers (Q&A)

In 1963 the World Health Assembly passed a resolution to *'examine ways and means of ensuring that drugs exported from a producing country comply with drug control requirements which apply in that country for domestic use.'* Years later the Certificate of Pharmaceutical Product (CPP), which gives countries some assurance from the exporting country regarding the quality, efficacy and safety of the product they are importing, has become one of the most essential reliance documents in the registration of medicinal products in over 80 countries¹. In recent years, with the globalization of the major drug companies, manufacturing may take place anywhere in the world and yet the CPP should still provide details concerning the manufacturer of the dosage form.

However, some countries interpret the WHO Certification Scheme¹ differently than the majority of CPP issuing countries and set certain conditions for issuing CPPs, e.g. manufacture and export from the issuing country to the requesting country, whereas most of the issuing countries provide CPPs for any approved pharmaceutical product.

CPPs are often required from the US FDA. Therefore, this paper gives some practical information on US FDA CPPs. The following questions and answers offer some clarification regarding these essential documents.

US CPP types

Q1: Does the US FDA issue CPPs?

A1: Yes. There are different types of CPPs depending on the approval status¹, manufacturing and export status of the product. The following CPPs can be issued:

Standard CPP

Drug product manufacturing, primary and secondary packaging must all take place in the US. The drug product must be exported from the US to the CPP requesting country. The supply chain approved in the US must be identical to the supply chain proposed in the importing country.

The CPP includes a GMP statement for the manufacturing site. It follows the format of the WHO Certification Scheme and is issued on

¹ Please refer to Q6 for non-approved products



IFPMA Questions & Answers

standard US FDA blue bubble paper with a RED ribbon and it is signed.

Foreign Manufacturer CPP

As the name of the CPP already indicates, the drug product is manufactured outside the US. However, primary and secondary packaging and export must take place in the US. The

supply chain approved in the US must be identical to the supply chain proposed in the importing country. The Foreign Manufacturer CPP includes a GMP statement for the foreign manufacturing site. The CPP is issued on standard US FDA blue bubble paper with a YELLOW ribbon and it is signed.

Table 1. Overview of CPP Types

| | Standard CPP (Approved US FDA Product) | Foreign Manufacturer CPP | Non-Marketed CPP (Unapproved Product) | Drug Substance/ API |
|------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|------------------------------------------------------|
| Bulk Manufacture | In the US | Outside the US | In the US | In the US |
| Primary and Secondary Packaging | In the US | In the US | In the US | In the US |
| Supply Chain | US supply chain identical to importing country | US supply chain identical to importing country | US supply chain identical to importing country | US supply chain identical to importing country |
| Export of finished product | From the US to importing country | From the US to importing country | From the US to importing country | From the US to importing country |
| GMP Statement | Yes, included in CPP for manufacturing site | Yes, included in CPP for manufacturing site | Yes, included in CPP for manufacturing site | Yes, included in CPP for manufacturing site |
| Document Format | Standard FDA blue bubble paper (CBER) Electronic (CDER) RED ribbon | Standard FDA blue bubble paper (CBER) Electronic (CDER)YELLOW ribbon | Standard FDA blue bubble paper (CBER) Electronic (CDER) BLUE ribbon | Electronic (CDER) ORANGE ribbon |



IFPMA Questions & Answers

Foreign Exported CPP

Q2: What is a status of Foreign Exported CPP?

A2: Previously called a pilot US CPP, the Foreign Exported CPP (FE CPP) was the CPP issued for drug products manufactured outside the US, where primary and secondary packaging also takes place outside the US and the product is not exported from the US. However, in 2020 US FDA decided to stop issuing of this type of CPP, due to the lack of a legislative mandate within the US FDA that is required to support the program. The information about this program cessation is also published under following link: <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-exports>.

Existing Alternatives to the FE CPP

1. The issuance of a 90-day Decisional Letter

- US FDA now formally issues Inspection classifications to facility owners within 90 days of the end of an inspection per [GDUFA/PDUFA](#) commitments, in the form of email.

2. The issuance of a Market Authorization (MA) Letter

- After a MA is issued, US FDA provides a US FDA MA Letter.

The **90-day Decisional Letter**, along with the **US FDA MA Letter** should satisfy the intent of the FE CPP.

Other Resources

Further resources for information to enable stakeholders verify whether:

- **a product is US FDA approved** are:

- The [ORANGE BOOK](#) (contains information about drugs, including biological products, approved for human use in the United States, except about US FDA-approved products regulated by the Center for Biologics Evaluation and Research), and

- The [PURPLE BOOK](#) database (contains information on all US FDA-licensed (approved) biological products, all US FDA-licensed allergenic, cellular and gene therapy, hematologic, and vaccine products).

- **US FDA's classification of its inspection of foreign facilities** is compliant with cGMP: [FDA INSPECTION CLASSIFICATION DATABASE](#).

All mentioned resources are publicly available databases, and the US FDA links are provided for reference.

Issuing authority

Q3: Who is the CPP issuing authority in the US?

A3: US FDA is the issuing authority, although the guidance states that it represents the current thinking of US FDA and they are not bound by the guidance. It is made noted that alternative approaches may be used, if these



IFPMA Questions & Answers

conform to the appropriate statutes and regulations. Applicants are encouraged to approach US FDA to discuss alternative approaches.

Q4: What information needs to be provided to the issuing authority?

A4: A request form needs to be completed. Details can be taken from the US FDA Guidance document on the [US FDA website](#).

As in any other country, only the marketing authorization holder can apply for a CPP.

Prerequisites

Q5: What are the conditions for obtaining US FDA CPP?

A5: US FDA issues the types of CPPs as described above for human drugs and biologicals, animal drugs and devices for products which may be legally marketed in the US or may be exported from the US, even if these products may not be marketed in the US. In the latter case the CPP contains a notation that the product is not marketed in the US. Single certificates can be issued for products approved with the same NDA number and the same dosage form but with different potencies.

US FDA will also issue certificates for products manufactured outside the US. The product must, however, be exported from the US to the receiving NRA (see Table 1).

Q6: Can I get a US CPP for a product which is not approved in the US?

A6: Yes, in 1996, the Export Reform and Enhancement Act² was amended to allow the issue of “export certificates” for products which are not approved in the US. The CPP contains a special comment that the product is not approved.

The CPP is issued on standard US FDA blue bubble paper with a BLUE ribbon.

Q7: What is the difference between a US CPP and an US FDA export certificate?

A7: US FDA issues a variety of export certificates, the Certificate of Pharmaceutical Product (CPP) is the only one for pharmaceutical products. The other certificates include Free Sales certificates (Certificate of Export for Seafood), Health Certificates for Food/Feed, Non-Clinical Research Use only Certificates, Specified Risk Materials of Bovine, Ovine and Caprine Origin Certificates, Certificate to Foreign Government and the Certificate of Exportability; none of which are issued for pharmaceutical products.

Q8: Is it possible to provide the artwork to US FDA instead of actual packaging material for US CPP issuance?

A8: Yes, the US FDA can accept either PDF or hard copy.

Format

Q9: Does the US CPP follow the WHO guideline/format?

A9: Yes, the US CPP conforms to the format dictated by the WHO certification scheme.



IFPMA Questions & Answers

Q10: What are the attachments included by default in any US CPP?

A10: US packaging components (outer carton, package/container label and package insert) are mandatory attachments. Product composition and approved shelf-life constitute optional attachments.

Q11: Can foreign trade names be included in CPP?

A11: Foreign trade names for the pharmaceutical products may be included and noted as "International Trade Names" in the remarks section of the CPP.

GMP status

Q12: Is the GMP status of the manufacturer declared in the US CPP?

A12: Yes, US FDA will not issue a certificate if the manufacturing facilities do not comply with GMP regulations, unless the product is not affected by the specific GMP deficiencies.

Issuance and validity times

Q13: How long does it take to get a US CPP and what does it cost?

A13: US FDA will issue a CPP within 20 government working days. A fee will only be charged if the certificate is issued within this specified time. The current fee for a CPP can be found on the [US FDA website](#)³, and it may vary according to the type of certificate requested. Subsequent certificates for the same country are issued at a reduced cost.

Q14: How long are the US CPPs valid?

A14: The CPPs issued by US FDA expire 24 months after the date of the CPP. An expiry statement is included in the document.

Scope exclusion

Q15: When will US FDA not issue a CPP?

A15: US FDA will not issue a CPP under certain conditions:

- if the product does not fulfill the requirements of the Export Reform and Enhancement Act;
- if the manufacturer has had an enforcement action initiated against them if the manufacturer fails to comply with GMP regulations
- if the manufacturing facility is not registered with the US FDA; or

if the product is not directly exported from the US to the requesting country.

Q16: Does the US FDA accept electronic applications for CPP?

A16: The US FDA accepts electronic CPP applications via the CDER Export Certification and Tracking System, and Biologics Export Certification application and Tracking system. An online Account ID (FURLS) is needed to request certificates electronically. (See Reference page for links)

Q17: How is the US FDA modernizing CDER's export certificate program?

A17: After December 3rd 2021 the US FDA CDER began issuing electronic Certificates of



IFPMA *Questions & Answers*

Pharmaceutical Product (eCPPs) and will no longer issue or mail paper CPPs. CPP applications received prior to December 3, 2021 will be issued as paper certificates. The eCPPs for human drug products will be issued as downloadable PDFs through the CDER Export Certification Application and Tracking System (CDER eCATS). The change from paper to electronic certificates will improve efficiency in issuing CPPs, reducing the amount of time it takes to receive export certificates, and decrease environmental burden.

The process for CPP submissions has not changed. Companies will continue to utilize CDER eCATS to submit CPP applications, and will be asked to provide an email address where the eCPP will be sent. Foreign

governments can continue to verify the authenticity of a manufacturer's export certificate through their CDER eCATS account, and from the spring of 2022, through the FURLS Export Certificate Validator (FECV) website.

US FDA will add a unique Quick Response (QR) code to the eCPP/export certificate. Foreign governments can reach the FECV site, by scanning the QR code on the eCPP. The eCPP is then verified by entering the unique eCPP number on the FECV website. The Agency anticipates this will enable faster exportation processing from the U.S. to the importing country.



IFPMA *Questions & Answers*

Disclaimer

This document is only for descriptive and informational purposes and reflects the most common experience of the IFPMA member companies on 10th February 2022.

National regulatory authority guidelines may be subject to change; for further details please consult the corresponding US FDA websites.

References

WHO Certification Scheme and Certificate of Pharmaceutical Product

<https://www.who.int/teams/regulation-prequalification/regulation-and-safety/rss/certification-scheme>

US FDA Export Certificates User Fees

<http://www.fda.gov/ForIndustry/UserFees/ExportCertificateFees/default.htm>

US FDA Export Certificates – Guidance for Industry

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm>

Certificate of a Pharmaceutical Product (CPP) Information on US FDA website – Links to Examples of Completed Form 3613b

<http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/importsandexportscompliance/ucm348825.htm>

US FDA Industry Systems/FDA Unified Registration and Listing Systems (FURLS)

<https://www.access.fda.gov/oaa/logonFlow.htm?execution=e2s1>

US FDA CDER Export Certification and Tracking System (CDEReCATS)

<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/ucm496247.htm>