

Variation: Application Details

Applicant's Ref: ICN Polfa GMP clearance
Status: Active
Original Tracking Number: MI-2019-CL-10131-1
Tracking Number: MI-2017-CL-01071-1
Variation Type: Renewals

Client Details

Variation Requests:
Select application type: MRA

Applicant Details

Applicant Name: iNova Pharmaceuticals (Australia) Pty Ltd
Client Id: 436
Address: PO Box 5033
Suburb: WEST CHATSWOOD
Postcode: 1515
State: NSW
Country: Australia

Sponsor

Sponsor Name: iNova Pharmaceuticals (Australia) Pty Ltd
Client Id: 436
Address: Level 10 12 Help Street
Suburb: CHATSWOOD
Postcode: 2067
State: NSW
Country: Australia

Contact Details

Contact Name: Brett Robinson
Phone: 02 9875 6246
Mobile:
Email: b.robinson@inovapharma.com
Fax: 02 9875 6477

Existing Manufacturer

Manufacturer Name: ICN Polfa Rzeszow SA
Manufacturer ID: 40909
Existing Manufacturing Site:
Manufacturer Site: 39-959 Rzeszow Ul Przemyslowa 2
Manufacturer Site ID: 54047
Suburb:
Postcode:
State:
Country: Poland

API/Product Details

Product	<u>Manufacturer Type</u>	<u>Sterility</u>	<u>Manufacturing Class</u>	<u>Dosage Form</u>	<u>Product Code</u>	<u>Manufacturing Steps</u>
Medicine manufacture	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Semi Solids	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Liquids	Registered Therapeutic Good	Finished Product Manufacture

Evidence

Is this GMP Clearance application related to a product listing/registration submission or variation of an Australian Register of Therapeutic Goods (ARTG) entry? N
Is this a Compliance Verification Assessment? N
In the Evidence to be provided are you using a Letter of Access to Clearance or Evidence? N

Supporting Documents

Mandatory Certificates or Letters

1 Current GMP Certificate Upload Evidence
-File Name: 1 Certificate ICN Polfa GMP (liquids & semi-solids) (inspection Apr 2019).pdf
-Last Inspection Date: 11/04/2019

Optional Evidence

<input type="checkbox"/> 12 Manufacturer's declaration for Active Pharmaceutical Ingredients (APIs)	Select delivery method
<input type="checkbox"/> 13 Certified translation statement	Select delivery method
<input type="checkbox"/> 14 Copy of the certificate of registration or a letter from the registrar in the manufacturer's country confirming the change of name	Select delivery method
<input type="checkbox"/> 15 Cover letter detailing extension request & reason	Select delivery method
<input type="checkbox"/> 16 Cover letter requesting change	Select delivery method
<input type="checkbox"/> 17 Botanical ingredients evidence for authenticated standard reference materials	Select delivery method
<input type="checkbox"/> Other	Select delivery method

Conditions

Expiry Date: 11/10/2022

Conditions:

Declaration

In submitting this application on behalf of iNova Pharmaceuticals (Australia) Pty Ltd, I **DECLARE** that:

- I am a person authorised to make this application; and
- this application, and any supporting material provided with this application, does not contain any information that is inaccurate, false or misleading.

Further, I **UNDERSTAND** that:

- giving inaccurate, false or misleading information, or omitting to give information in relation to a material particular, is a serious offence under the Criminal Code Act 1995.

By clicking on the Agree button below, I **AGREE** with all of the above statements.

Agree

We encourage applicants to save a copy of their application prior to submitting their application.