

**DSS HC Document  
FORM -02816 – Revision 3**

To be used with valid version of WI-02252 – Creation of LOAs



**Letter of Authorization (LOA request form)**

Please fill out as complete as possible- if you have questions please contact regulatory-affairs@datwyler.com or call + 32 (0) 11 59 08 11

Date	
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**1. Requesting Company Information:**

Name	
Job title	
Company name	
Street address	
City	
State / Province	
Zip / Postal code	
Country	
E-mail	
Phone	

**2. Information on Company for whom LOA is being issued (if different from above)**

Company name	
Street address	
City	
State / Province	
Zip / Postal code	
Country	
Name	
Job title	
E-mail	
Phone	

**3. Submission Details:**

A. New Drug Product Registration	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
B. Update in existing LOA	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If B is yes then - Existing LOA number - Change of name or address	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
C. Submission Country	<input type="checkbox"/> USA	<input type="checkbox"/> Canada	<input type="checkbox"/> China (PRC)

# Letter of Authorization (LOA request form)

Please fill out as complete as possible- if you have questions please contact regulatory-affairs@datwyler.com or call + 32 (0) 11 59 08 11



If submission country is **USA** (fill this section)

Drug Product Name	
Application type	<input type="checkbox"/> ANDA <input type="checkbox"/> NDA <input type="checkbox"/> IND <input type="checkbox"/> BLA <input type="checkbox"/> Other If other Please specify
Datwyler Product code (11 code)	
If no Datwyler product code is available to you, please complete the Compound and Washing program information below	
Compound of Datwyler product	
Washing program	<input type="checkbox"/> ISAF <input type="checkbox"/> FLNC <input type="checkbox"/> FLCO <input type="checkbox"/> ISDC <input type="checkbox"/> Other If other please specify

If submission country is **China** (Fill this section)

Drug Product Name (in English)	
Drug Product Name (in Chinese)	
Company / Marketing Authorization holder name (in Chinese)	
Type of drug product	<input type="checkbox"/> import <input type="checkbox"/> local production in China
The drug product is an injectable	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other If other please specify
Route of Administration (if required)	<input type="checkbox"/> Intramuscular <input type="checkbox"/> Intravenous <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Other If other please specify
Datwyler Product number or code or name or type	

If submission country is **Canada** (Fill only this section)

Drug Product Name	
Datwyler Product code (11 code)	
If no Datwyler product code is available to you, please complete the Compound and Washing program information below	
Compound of Datwyler product	
Washing program	<input type="checkbox"/> ISAF <input type="checkbox"/> FLNC <input type="checkbox"/> FLCO <input type="checkbox"/> ISDC <input type="checkbox"/> Other If other please specify

Datwyler Account Manager Name	
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