





Patheon is a leading provider of contract development and commercial manufacturing services to the pharmaceutical & biotechnology sectors.

We offer the broadest set of solutions to clients including development and commercial manufacturing services for both large and small molecule drug substance and drug product in a wide range of dosage forms.



Inspire & Simplify.





Single Source Provider, End-to-End





Single Source Provider, End-to-End





Single Source Provider, End-to-End





A Recognized Leader in Contract Development and Manufacturing



The contract development market was worth \$1.9B in 2013

Patheon is the market leader with a 9% share



The highly fragmented manufacturing market was worth \$15.1B in 2013

Patheon is second in the market with a 7% share

¹Source: PharmSource estimates, 2014. Development market estimate includes preformulation, formulation, and clinical dose manufacturing. ²Source: PharmSource estimates, 2014. Contract Manufacturing market estimate excludes enhanced packaging. Includes DPP data

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Patheon is a Global Service Provider

More than 25 locations across North America, Europe, Latin America & Australia



As of April 2015

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Patheon Bourgoin Overview



✓ Pharmaceutical site since 1960'✓ PATHEON site since1999

✓ Manufacturing Area: 25 250 m²
 ✓ Employees: 262 (Commercial) + 50 (Development Services)

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Bourgoin Overview

Site authorized and focused on High-potent compounds (up to Cat3B)



PDS (Development) co-located with commercial plant (DPS).

Solid oral dosage forms manufacturing

Compatible processes to allow smooth scale up of solid dose manufacturing processes from

- ✓ clinical batches and small commercial batches (5 150 kg) to
- ✓ larger commercial (150 750kg) process scales

EU Center of Excellence Packaging: blisters, bottling, sachets

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Regulatory and inspection history

- The Bourgoin facility is routinely inspected by both its international clients and its local Regulatory Body – ANSM.
- ANSM approved site (June 2014)
- US FDA approved site (March 2014)
- PMDA accreditation (Japanese authority) (February 2012)
- The facility is approved for all European countries, Canada, New Zealand, Australia, Kenya and Japan through mutual recognition (MRAs)
- Shipment to worldwilde destinations such as, Asia, MEAF, South America etc.

Date of Inspection	Regulatory Authority	Inspection Type		
Nov 2015	ANSM	GMP		
June 2015	ANVISA	GMP		
March 2015	Kenyan Inspection	GMP		
November 2014	Turkish Inspection	GMP		
June 2014	ANSM (France)	GMP		
March 2014	FDA	PAI		
December 2013	Turkish Inspection	GMP		
April 2012	ANSM (France)	GMP		
July 2011	ANSM (France) for PDS	GMP		
November 2009	ANSM (France)	GMP		
November 2008	KFDA (Korea)	PAI		
July 2008	GISK (Russia)	GMP		
June 2008	ANVISA	GMP		

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Product Development Services Growth *Built in 2010 – Started in 2011*



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High Potent Oral Solid Dose Center Of Excellence

Seamless contained development and manufacturing service

- Safely APIs process with a minimum OEB 4 / OELs >10 ng/m³ (Cat 3b)

-Contained processing design concept to minimise the need for PPE (personal protective equipment) for routine operations. Compliant with Big Pharma HiPo Health-Security-Environment internal rules

- Design-for-manufacture approach enabling reproducibility from development scale (1kg) to commercial scale

	Ca	t4		Cat 3B		Cat 3A	Cat	2	Cat 1	
^{EOB 5} 10 r		10 rg	g/m³	EOB 4	1 ug/	'm³ 10 uç	ıg/m³ 1		mg/m³	



Bourgoin Development Services Capabilities

Technologies

- High potency containment at source
- Powder blending (5 150 kg)
- Granulation (30 150 kg)
- Dry compaction
- Compression (conventional, minitabs & bilayer tablets)
- Coating
- Encapsulation

Packaging

- Semi automatic packaging lines:
 - Bottles
 - Blisters (PVC, PVDC, Aclar®)

Dosage forms

- Tablets
- Capsules
- Sachets
- Oral Solutions

Services

- Clinical supply
- Process Development
- Quality by Design
- DoE
- Small scale commercial supply



Exemples de produits hautement actifs novateurs développés sur le site de Bourgoin-Jallieu

Projet P232: traitement du cancer du myélome, Leucémie aigue (US)
Projet P470: traitement du cancer de la prostate (US)
Projet P448: traitement du cancer de la prostate (Finland)
Projet P549: traitement des tumeurs solides, cancer du sein / des poumons, (France)
Projet P497: traitement de la leucémie aigue (Japan)
Projet P513: traitement de la maladie de Parkinson (Switzerland)
Projet P460: traitement du cancer du sein (US)





Contact

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