PAN CELLTECH™

CASE STUDY

CASE STUDY · CMO / CDMO

A PRIVATE-LABEL GMP LINE FOR EUROPE

Prepared by **PAN-Biotech**

Author:
Valentin Knab, Head of GMP & Custom Solutions
6 Aug 2026 · Anonymised customer story

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A PRIVATE-LABEL GMP LINE FOR EUROPE

A global, Japan-headquartered company wanted to launch a private-label product line for European customers – without building a plant. PAN-CellTech provided a tailored CMO/CDMO model: GMP (EU Annex 1) process development, customised single-use packaging and full QC/QA.

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Results at a glance

- **GMP (EU Annex 1)** · custom-formulated products to GMP in an EU Annex 1 facility
- **Custom single-use packaging** · bags or bottles to fit the partner's GMP workflows
- **Full QC / QA** · testing and QA documentation to European standards
- **Ongoing supply** · an active CMO / CDMO relationship

This story is published with the customer **anonymised**. It describes a real PAN-CellTech CMO/CDMO engagement; the customer's name is withheld.

THE CONTEXT

A global brand entering Europe

A global, Japan-headquartered company set out to launch a private-label product line for European customers. Building a European facility, learning a new regulatory system and running production in-house would have turned a market-entry decision into a multi-year capital project.

THE CHALLENGE

Custom GMP products, fully compliant, fully integrated

They needed a European CMO/CDMO that could produce custom-formulated products under GMP (EU Annex 1), guarantee full regulatory compliance, and integrate seamlessly into their existing GMP production environments – so the private-label line could reach European customers without the build.

THE SOLUTION

A tailored CMO/CDMO model

PAN-CellTech built a service model on flexibility, compliance and trust:

- **GMP-compliant production-process development**, for both new and existing products.
- **Customised packaging formats** in single-use bags or bottles, designed to fit the partner's GMP workflows.
- **Full QC testing and QA documentation** to meet European pharmaceutical standards.
- **Delivery to the partner's designated EU production site.**

THE RESULT

Market access without building a plant

A flexible, compliant, trusted model let a global manufacturer put its own label on GMP products made in the EU – market access without building a plant. The engagement is an ongoing CMO/CDMO supply.

THE ENGAGEMENT

The project at a glance

PARAMETER	DETAIL
Customer	Global company, Japan-headquartered – anonymised
Objective	Private-label product line for European customers, without building a plant
Model	Tailored CMO / CDMO engagement with PAN-CellTech
Standard	GMP, manufactured in an EU Annex 1 facility
Process development	GMP-compliant, for both new and existing products
Packaging	Customised single-use bags or bottles, fitted to the partner's GMP workflows
Quality	Full QC testing and QA documentation to European pharmaceutical standards
Delivery	To the partner's designated EU production site
Status	Ongoing CMO / CDMO supply

FAQ 1

How can a non-EU manufacturer produce a private-label GMP line in Europe without building a facility?

By partnering with a European CMO/CDMO that develops the GMP production process, manufactures to GMP in an EU Annex 1 facility, provides custom packaging and full QC/QA documentation, and delivers into the partner's EU site.

FAQ 2

Can PAN-CellTech develop the GMP production process for both new and existing products?

Yes. The model includes GMP-compliant production-process development for new and existing products, plus customised single-use bag or bottle packaging designed to fit the partner's GMP workflows.

FAQ 3

What quality documentation is provided?

Full QC testing and QA documentation to European pharmaceutical standards, with delivery to the partner's designated EU production site.

Bringing a private-label or custom GMP line to Europe?

PAN-CellTech can develop the process, manufacture to GMP in an EU Annex 1 facility, and integrate into your GMP workflows – so you reach European customers without the build.

Start a Custom & GMP Project Enquiry: pan-biotech.com/custom-gmp-project-enquiry/ · **info@pan-celltech.com**

PAN-Biotech GmbH · Manufacturer of record for GMP supply: PAN-CellTech GmbH (EU Annex 1) · Customer anonymised. GMP-compliant, audit-proven manufacture; EU Annex 1 is a capability, not a certification.