PromoCell

# GMP offerings

Transitioning *in vitro* research to clinical applications seamlessly

# Introducing our Custom GMP Services — designed for safety, consistency, and regulatory compliance

We recognize the growing demand for cell culture media in regenerative medicine and cell therapy that goes beyond standard offerings. At PromoCell, we bridge the gap between discovery and clinical implementation with Excipient GMP-grade media manufacturing tailored for research institutions, biotech organizations, and **red biotechnology innovators**.

Since 1990, we have established ourselves as a trusted partner in biomedical research, providing high-quality cell culture products that meet high research standards. With over 35 years of experience in human primary cells, stem cells, blood cells, and cell culture media and reagents, we bring this expertise to Custom GMP Services specifically designed to accelerate red biotechnology innovation by supporting developers of cell therapies, regenerative medicine approaches, and personalized treatment solutions.

Our Custom GMP Services are developed within a quality management system in compliance with the EXCiPACT™ GMP certification scheme for pharmaceutical excipients or Pharmaceutical Auxiliary Materials (PAMs). **Serving the needs of red biotechnology, including those developing cell-based therapies and regenerative medicine approaches, we understand the critical importance of reliable, high-quality cell culture media in enabling clinical translation.** Designed to meet the demanding requirements of cell therapy and regenerative medicine, our new Custom GMP Services reflect our commitment to supporting research institutions and biotech innovators in advancing cell therapies, regenerative medicine, and red biotechnology — from fundamental research through clinical implementation. Every custom solution is produced under **traceable processes** and comes with **comprehensive documentation** to support risk assessments. To complement our Custom GMP Services, we also offer the PromoExQ line of off-the-shelf (OTS) Excipient GMP-grade cell culture products that showcase our manufacturing capabilities and provide immediate solutions for common research needs.

## Custom GMP Services

We support complex and custom requirements with our GMP service capabilities to match your specific cell type and therapeutic goals. As your partner, we bridge the gap between groundbreaking discovery and clinical implementation with services specifically designed for research institutions, biotech organizations, and red biotechnology innovators. Going beyond the standard media typically available, we offer an extensive range of specialized formulations tailored to a diverse array of cell types including stem cells, endothelial cells, fibroblasts, and muscle cells.

**Our customizable formulations and packaging options include:**

- **Tailored Excipient GMP-grade media:** Modifications in formulation, quality control testing, scalability, backed by 35 years of expertise in cell culture.
- **Flexible packaging:** From bottles to custom-sized bags, we adapt to your process needs.
- **End-to-end efficiency:** Streamlined processes with optimized media formulations.
- **Certified manufacturing environment:** Manufacturing site with a EXCiPACT™ certified quality management system.

| Benefits of Custom GMP Services | |
|---|---|
| **Customized formulation** | Custom formulation available based on our existing cell culture media formulations |
| **Batch-specific quality control (QC) testing** | **Standard testing included in the Certificates of Analysis (CoA)**<br>■ Color/clarity<br>■ Microbial contamination<br>■ Functionality<br>■ pH<br>■ Osmolality<br>■ Endotoxin level in basal medium ≤ 1 EU/mL<br>■ Mycoplasma<br>**Additional quality control (QC) testing possible** |
| **Batch volumes** | 10 – 200 L |
| **Packaging sizes** | Standard packaging (125 mL / 500 mL bottle) or custom packaging (1 L bottle, 5 L – 20 L media bag) available |
| **Label** | Customization of the label possible (e.g., add manufacturing date, data matrix code) |
| **Traceability** | Information about changes in compliance with the IPEC Significant Change Guide for Pharmaceutical Excipients |
| **Stability** | Stability study possible for the requested customized medium (formulation and packaging) for a requested time frame |

## Why choose custom services?

- **Personalized solutions:** Media tailored to your specific cell type and research needs.
- **Scalability:** Solutions designed to grow with your research and clinical applications.
- **Quality assurance:** Rigorous testing and documentation to ensure compliance and consistency.

## A partnership from start to scale

From research through clinical translation, our workflow ensures reproducibility, reliability, and peace of mind. We work alongside researchers and biotech organizations to create a customized solution to meet your project's unique needs.

Research and discovery

Translational

Non-GLP preclinics

GLP preclinic

Clinical trials

Phase I clinic

Phase II/III clinic

Market introduction

Human primary cells and media for research use only

↓ Your journey for Excipient GMP-grade media starts here ↓

| | Full service | Scale up | Fast track with OTS products |
|---|---|---|---|
| It starts with listening | We begin by listening to your needs and mapping out your process together. With a personal project manager assigned to you, we ensure a structured and transparent process – from initial request to final delivery. | | |
| Together, we find the perfect fit | We believe the best solutions are built together. Our experts collaborate closely with you to understand your specific requirements and identify the most suitable option from our PromoExQ portfolio. When off-the-shelf (OTS) products aren't the perfect fit, we draw on our proven formulations to develop customized media tailored to your application. Together, we'll create a solution that meets your exact needs. | | Proceed with OTS media. |
| Fine-tuning for confidence | Once we've defined your tailored solution, we move into pilot production, where small-scale batches are developed to test performance and compatibility within your process. This collaborative phase allows us to fine-tune the formulation and ensure it meets all functional and regulatory expectations. Together, we evaluate that your custom medium is ready for the next step. | Scale up OTS media. | |
| Taking the next step: Full-scale manufacturing | Once approved, we move forward together into full-scale production. All media manufacturing is carried out in our site with a EXCiPACT™ certified quality management system. Our focus is on ensuring consistency, quality, and regulatory alignment—so you can move ahead with confidence, knowing your product meets the highest standards. | | |
| From our facility to your workflow | With your custom media manufactured at full scale, we ensure it's packaged securely and delivered reliably—on time and in the format that fits your workflow. But our partnership doesn't end at delivery. Your dedicated project manager remains available to support you with any follow-up needs, adjustments, or future projects. We're here for the long term—committed to your success at every step. | | |

# Our off-the-shelf Excipient GMP-grade media

PromoExQ media represent our premium Excipient GMP-grade cell culture solutions, manufactured at our site with a EXCiPACT™ certified quality management system with complete traceability. These ready-to-use media are available in both serum-containing and xeno-free options, supporting diverse cell types including MSCs, HPCs, fibroblasts, and pericytes. The product undergoes rigorous quality testing for functionality, endotoxin, and mycoplasma, with comprehensive documentation to support regulatory relevant risk assessments. Our PromoExQ portfolio features specialized formulations that maintain optimal cell viability, phenotype stability, and expansion capabilities while facilitating seamless translation from research to clinical applications without reformulation.

**Our comprehensive list of Excipient GMP-grade media includes the following specialized media:**

**PromoExQ MSC Growth Medium XF (prf)**
EQ-C-28018

- Serum- and xeno-free
- Phenol red-free
- *In vitro* expansion of human MSCs from the bone marrow, umbilical cord matrix (Wharton's jelly), and adipose tissue

**PromoExQ Mesenchymal Stem Cell Growth Medium 2 (prf)**
EQ-C-28017

- Phenol red-free
- Isolation and expansion of MSC from bone marrow, the umbilical cord matrix (Wharton's Jelly), and adipose tissue
- No coating required

**PromoExQ HPC Expansion Medium XF (prf)**
EQ-C-28022

- Serum-free and xeno-free: Ensures batch-to-batch uniformity and minimizes experimental variability
- Ready-to-use: Fully supplemented medium including a premixed cytokine mix for $CD34^+$ expansion
- Increased $CD34^+$ yield: Optimal expansion of human hematopoietic progenitor cells with a typical 50–200-fold increase of $CD34^+$ progenitor cells

**PromoExQ Fibroblast Growth Medium D-ACF (prf)**
EQ-C-23017

- Defined and animal component-free: Developed and optimized for juvenile NHDF, also suitable for adult NHDF
- Population doublings: 15 population doublings in adult and juvenile NHDF, with doubling time of juvenile NHDF comparable to that of cells grown in conventional medium
- Marker support: Supports CD90 expression in PromoCell NHDF up to 15 population doublings

**PromoExQ CellNAP**
EQ-C-29930/EQ-C-29932

- Antioxidant technology: Preserves cell viability, attachment, and growth
- Minimal freeze damage: Protects cell samples during freezing and thawing, offering maximum recovery
- Versatile: Suitable for various cell types, including sensitive cell types (e.g., primary cells, stem cells, iPSC)

**PromoExQ Pericyte Growth Medium 2 (prf)**
EQ-C-28042

- Serum-containing, phenol red-free
- *In vitro* expansion of human pericytes from all tissues
- No coating required

We have more in the pipeline — **get in touch to learn more: gmp@promocell.com**

# Compliance without compromise

## Why choose custom services?

**Comprehensive documentation:** Accelerate risk assessments and regulatory approvals with our documentation package.

**Expert support:** Our team is here to assist with audit-related questions or concerns, available in English and German.

**Regulatory compliance:** Ensure your cell culture media meets regulatory standards.

**Proactive raw material alerts:** Notifications of specification changes impacting compliance according to the IPEC Change Guide in its current version.

**On-time delivery:** Dedicated project timelines with contingency planning to mitigate downtime risks.

We provide a comprehensive documentation suite to support your risk assessments and regulatory submissions. Our GMP statements include:

- **Certificate of Analysis (CoA)**
- **Excipient quality assessment file (EQAF)**
- **Statements on GMP compliance, BSE/TSE status, GMO, and microbial and viral safety (MVS)**
- **Certificate of Origin (CoO)**
- **Declaration of conformity**

We also offer dual-language audit support:

- **On-site audits:** Conducted in English or German to simplify onboarding
- **Remote audits:** Convenient audit options
- **Documentation audits:** Comprehensive review of all necessary documentation

# Expert guidance: Your shortcut to GMP confidence

Navigating the transition from research to GMP-grade cell culture can be challenging, especially when developing innovative red biotechnology applications. Our scientific experts provide personalized, one-on-one guidance to map your workflow with clear, step-by-step support tailored to the unique requirements of cell therapy, regenerative medicine, and personalized treatment development. We also offer free educational tools, including infographics, blog articles, and whitepapers.

## Benefits of our expert support:

- **Simplified compliance:** Understand and meet GMP requirements specific to therapeutic cell culture applications with ease.
- **Accelerated research:** Focus on advancing red biotechnology while we handle to support the regulatory complexities of clinical translation.
- **Confidence in quality:** Ensure your cell culture media meets the highest standards of quality and consistency required for clinical translation.

## Compliance

Our Quality Management System is certified according the EXCIPACT™ GMP standard.

ISO 9001:2015 certification ensures that we "consistently provide products and services that meet customer and applicable statutory and regulatory requirements".

## How to get in contact with us

Trying to navigate GMP requirements while advancing your primary cell research? Our Custom GMP Services and products are designed to seamlessly transition from discovery to clinical applications and beyond, ensuring you have the resources you need at every stage of your journey.

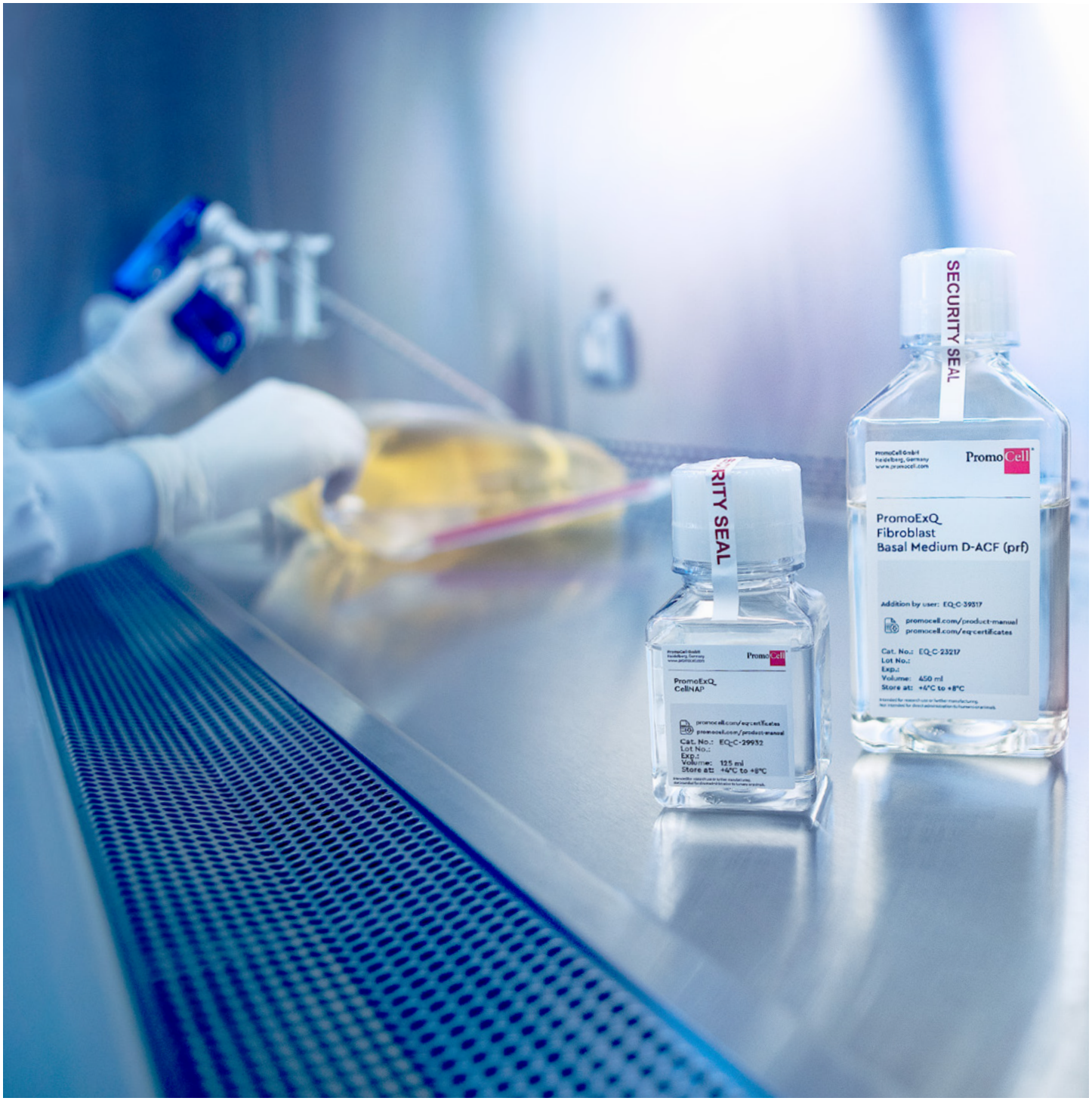
### Partner with us to accelerate innovation in life sciences and biotechnology:

- **35 years of expertise:** With decades of experience in primary cell culture media, we understand the challenges and requirements of cell therapy and regenerative medicine.
- **EXCiPACT™ GMP standard:** Our products are manufactured in our manufacturing site with a EXCiPACT™ certified quality management system. Additionally, the EXCiPACT Standard 2025 provides a robust quality framework for materials indirectly used in pharmaceutical manufacturing, such as processing aids, buffers, and cleaning agents. This standard brings together the key requirements for these materials, helping to ensure consistent quality, safety, and regulatory compliance of PAMs.
- **Partnership:** From research to clinical applications, we provide the resources and support needed at every stage of your journey.

### Order information:

**Off-the-shelf products:** Contact **info@promocell.com** for immediate access to our standardized Excipient GMP-grade media portfolio and product specifications.

**Custom GMP Services:** Reach out to **gmp@promocell.com** to discuss your specialized formulation needs and begin your tailored GMP media development journey.




*"GMP grade" is a branding term used by PromoCell to denote reagents that are manufactured at the PromoCell manufacturing facility in Heidelberg, Germany, under strictly controlled processes to meet stringent product specifications and customer requirements. Reagents manufactured at PromoCell are produced according to EXCiPACT™ GMP standards, a quality management system that builds on our ISO 9001:2015 certification. Risk assessment procedures are carried out at the customer site.

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