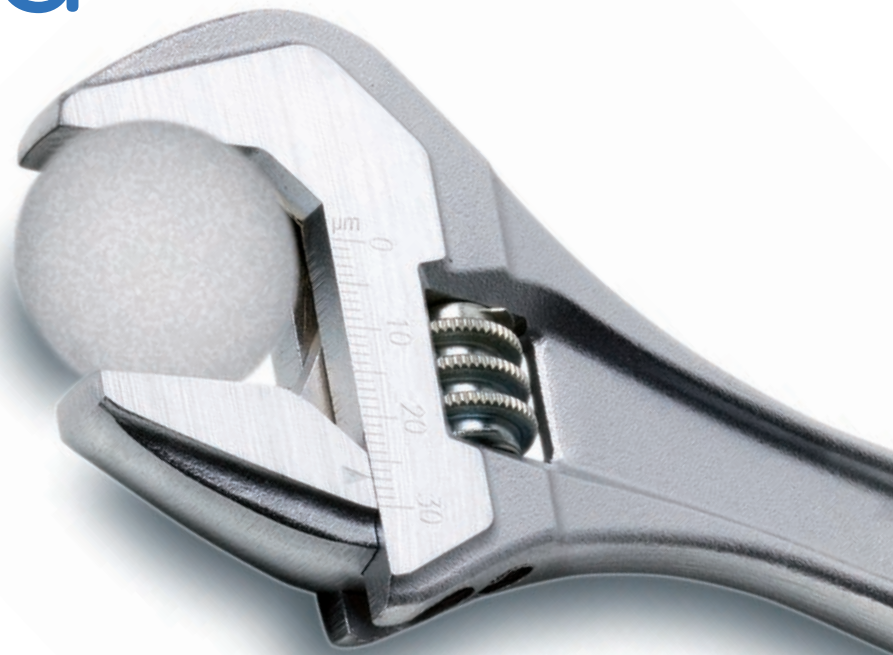
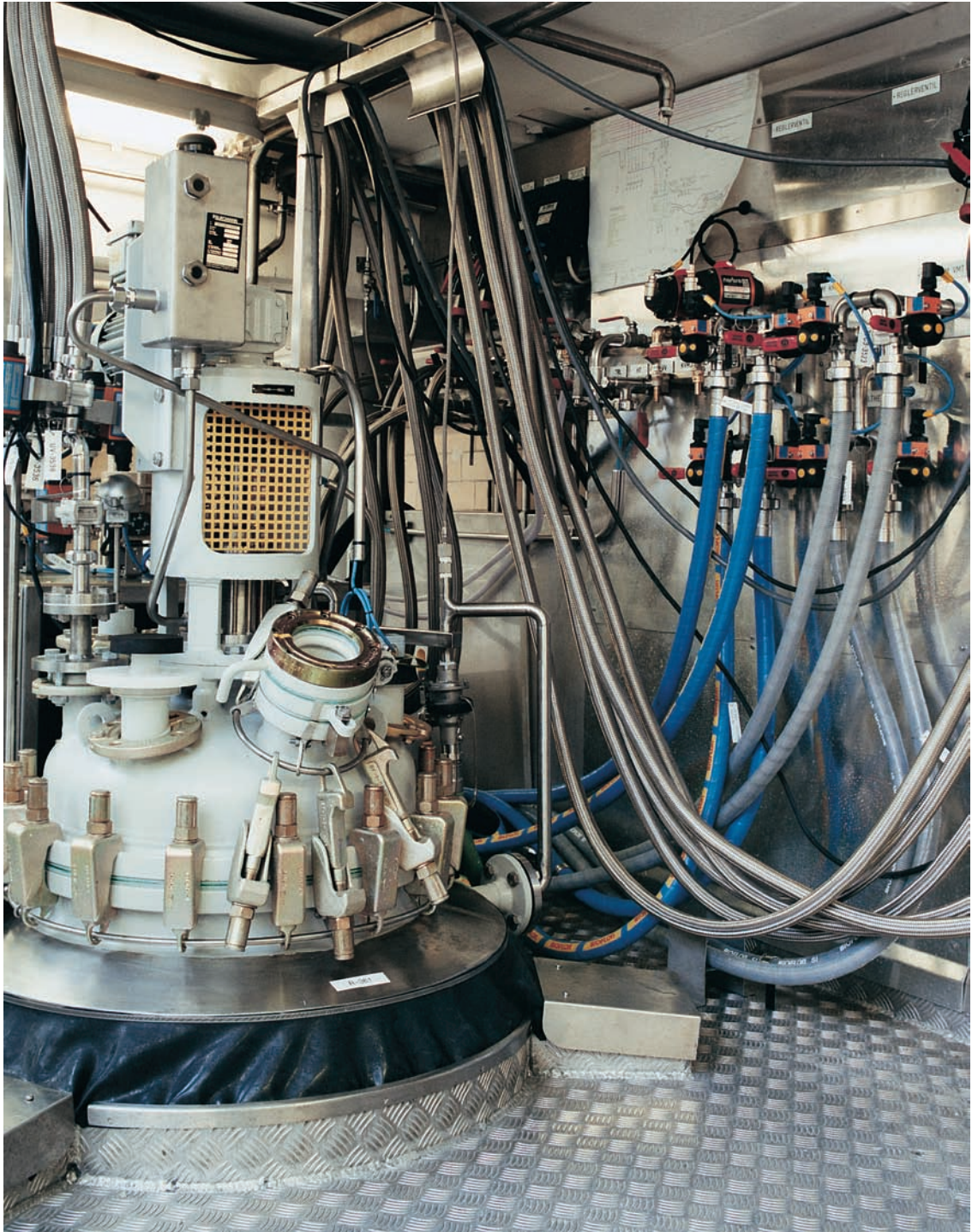


When nothing else works

Custom  
Designed  
Media





# Standard solutions don't always work

Standard media don't always give the results you hope for. You've tried everything to improve your process yet problems with poor selectivity and purity persist; moreover you suspect that the ligand you are using is "not up to the job".

Custom Designed Media (CDM) can provide powerful solutions to special situations where standard media do not give optimal performance. By tailoring a chromatography medium for your specific problem a CDM project aims to give you a more robust process and improved economy.

By working in close collaboration with one of our experienced project managers, CDM projects start with a face-to-face meeting followed by regular contacts to keep the ball rolling. We also respond at the pace you require; projects can go from start to validated production in as little as six months.

# Leave your problems behind with CDM

The CDM group provides large scale operators with chromatography media designed for their specific purification tasks. CDM has the distinctive capability of combining GE Healthcare's reliability and production capacity with rapid development and flexibility.

By working together we can quickly respond to your needs. Our design processes are ISO 9001 certified and on completion you are supported with documentation packages to ease the registration process to production.

When you are up and running you can be sure that CDM media are produced with the same high quality as other GE Healthcare BioProcess™ media and with security of supply.





# Our toolbox



When making a custom design medium, all the different design parameters are considered to give the best possible result. Selectivity can be improved by providing new ligand designs or by optimizing ligand density and spacer structure. Throughput, capacity, or resolution can be maximized by the type of base matrix as well as spacer and ligand density.

During the design process, three components can be optimized to give the desired function: the base matrix, the spacer and the ligand.

## Ligand



The choice of ligand is crucial for obtaining the right selectivity and is a key aspect of the CDM collaboration. Any type of ligand can be used, from short carbon chains in HIC media, to large proteins in affinity media.

CDM also has libraries of propriety mixed mode ligands available for screening by the customer, to find a suitable selectivity.

## Linker



Linker arms and coupling chemistry can be varied from low to high density and from short linkers to long dextran polymers depending on the application.

## Matrix



CDM uses all available base matrices from GE Healthcare such as, Sepharose™, Sephacryl™, Sephadex™, STREAMLINE™, Capto™, and SOURCE™. The extensive range of different porosities and particle sizes will allow you to find the optimal base matrix for your application.

The agarose based matrices offers exceptional properties such as no unspecific binding and an open pore structure for rapid mass transport of proteins.

Typically, CDM media involve a new combination of an existing base matrix and ligand. The ligand may come from many sources, in house, bought from an external supplier or developed by the customer. Once a candidate is found, we design a medium for industrial use – with unique selectivity.

Our toolbox also includes libraries of mixed mode ligands covering a wide range of selectivities. These ligand libraries can be made available in multiwell plate format for evaluation by the customer, after discussions with CDM and after signing of a material transfer agreement (MTA).

# The CDM Project Model

A CDM project is run according to a well established and proven model, where we work in close collaboration with the customer, often under a confidentiality agreement. An experienced team works with the customer from the initial discussions right through to bulk delivery: establishing the needs, defining the product, and producing and testing the finished product.

## Media assurance

- Synthesis robustness
- Analysis methods
- Preliminary specifications
- Customer evaluation of samples
- Pilot scale delivery

## Media definition

- Define desired product function
- Decide type of matrix, ligand and coupling chemistry
- Customer evaluation of samples

1.



## Full scale production and validation

- Scale up
- Validation
- Regulatory Support Files
- Full scale delivery

### Three distinct phases

#### 1 Definition

After start of a project CDM designs prototypes targeting a specific customer problem, by introducing new ligands, spacers and base matrices. The prototypes (typically 25 ml samples) are evaluated by the customer, and if a working design is found, the next stage is entered.

#### 2 Assurance

A robust and scalable lab synthesis method is developed and analytical methods are developed, validated, and transferred to quality control. The product specifications are set together with the customer. The customer evaluates samples from the upper and lower ends of the specification to ensure robustness and function of the product in the full specification range. In this phase, scale up to pilot scale is done, typically using 10–20 l of medium.

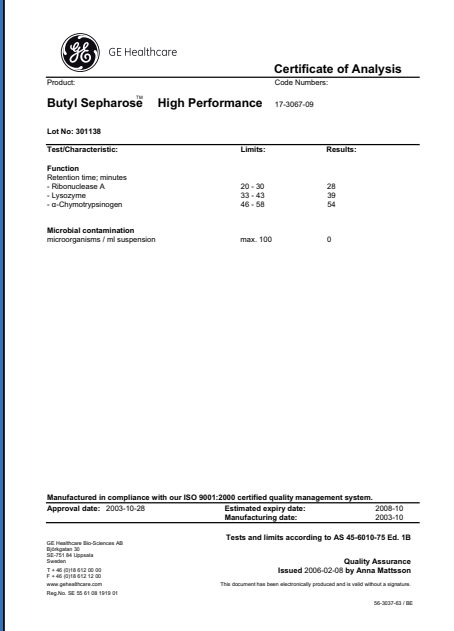
#### 3 Process validation

CDM scale up to a scale appropriate for the customer needs, with possibilities to work with batch sizes ranging from 10 up to 1000 liters. Validation of the production process is done concurrently with deliveries to the customer. Stability studies, shelf life studies and documentation needed for the RSF is produced.



# Stringent quality

Every CDM product is designed to meet the stringent quality standards for commercial industrial use. Each product undergoes full quality control, both during development and at full scale manufacturing. CDM products also come with the same documentation and regulatory support as for GE Healthcare standard media. According to the customer needs, we will establish regulatory support files (RSF) and other documents required for the registration process.



The image shows a Certificate of Analysis (COA) for Butyl Sepharose High Performance. It includes the GE Healthcare logo, product name, lot number (381138), and a table of test results. The table has three columns: Test/Characteristic, Limits, and Results. The tests include retention time for Ribonuclease A, Lysozyme, and Chymotrypsinogen, and microbial contamination. The document also mentions compliance with ISO 9001:2000 and AS 45-6010-75 Ed. 1B, and is signed by Anna Mattsson.

| Test/Characteristic:           | Limits:  | Results: |
|--------------------------------|----------|----------|
| <b>Function</b>                |          |          |
| Retention time, minutes        |          |          |
| - Ribonuclease A               | 20 - 30  | 28       |
| - Lysozyme                     | 33 - 43  | 39       |
| - $\epsilon$ -Chymotrypsinogen | 46 - 58  | 54       |
| <b>Microbial contamination</b> |          |          |
| microorganisms / ml suspension | max. 100 | 0        |

# Time is your investment

In most CDM projects, the product is developed on a non-exclusive basis, and you are only charged for the cost of larger media deliveries. No milestone fees are involved – you pay with your own time. Exclusive products, or products with no obvious uses outside your specific application may require development cost sharing.

# Success built on trust

With over 20 successful years of experience we have a proven track record in delivering reliable, high quality chromatography media. In fact, a substantial part of GE Healthcare's media portfolio originated from CDM media products.



Examples of well-known products from CDM include:

Butyl Sepharose 4 Fast Flow

Protein A Sepharose 4 Fast Flow

Blue Sepharose 6 Fast Flow

Octyl Sepharose 4 Fast Flow

NHS activated Sepharose 4 Fast Flow

CNBr-activated Sepharose 4 Fast Flow

Heparin Sepharose 6 Fast Flow

Phenyl Sepharose 6 Fast Flow (high sub)

Phenyl Sepharose 6 Fast Flow (low sub)

ANX Sepharose 4 Fast Flow (high sub)

Butyl Sepharose High Performance

Streamline Phenyl

Q Sepharose Big Beads

# Products available from CDM

## Ordering information

| Product                                      | Pack size | Code No.   |
|--|-----------|------------|
| 6-AKS Sepharose 4 Fast Flow                  | 1 l       | 17-3100-04 |
| Amino Sepharose 6 Fast Flow                  | 1 l       | 17-3092-09 |
| ANX Sepharose 4 Fast Flow (low sub)          | 500 ml    | 17-1286-01 |
|  | 5 l       | 17-1286-04 |
| AVB Sepharose High Performance               | 75 ml     | 28-4112-01 |
|  | 1 l       | 28-4112-02 |
| Benzamidine Sepharose 4 Fast Flow (high sub) | 100 ml    | 17-5123-01 |
|  | 500 ml    | 17-5123-02 |
|  | 5 l       | 17-5123-03 |
| Benzamidine Sepharose 4 Fast Flow (low sub)  | 5 l       | 28-4108-03 |
| Butyl Sepharose High Performance             | 1 l       | 17-5432-03 |
|  | 5 l       | 17-5432-04 |
| Butyl Sepharose 6 Fast Flow                  | 1 l       | 17-5431-03 |
|  | 5 l       | 17-5431-04 |
| Chelating Sepharose Big Beads                | 1 l       | 17-5272-03 |
|  | 10 l      | 17-5272-05 |
| CM Sepharose High Performance                | 1 l       | 17-1277-03 |
|  | 5 l       | 17-1277-04 |
|  | 10 l      | 17-1277-05 |
| ECH-Lysine Sepharose 4 Fast Flow             | 500 ml    | 17-0902-02 |
|  | 5 l       | 17-0902-04 |
| Gelatin Sepharose 4 Fast Flow                | 1 l       | 17-0976-03 |
|  | 5 l       | 17-0976-04 |
| IgG Sepharose 6 Fast Flow                    | 200 ml    | 17-0969-02 |
|  | 5 l       | 17-0969-04 |
| Phenyl Sepharose Big Beads                   | 1 l       | 17-5098-03 |
|  | 10 l      | 17-5098-05 |
| Plasminogen removal gel                      | 1 l       | 28-4109-03 |
| Procainamide Sepharose 4 Fast Flow           | 1 l       | 28-4111-03 |
|  | 5 l       | 28-4111-04 |
| IgSelect                                     | 25 ml     | 28-4113-01 |
|  | 1 l       | 28-4113-03 |

For further information, contact your local sales representative or visit:

[www.gelifesciences.com/cdm](http://www.gelifesciences.com/cdm)

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imagination at work