

interactive quiz and toolkit

# Water in pharma and healthcare

How much risk can you take?

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# Lab water contamination is **avoidable**

This interactive document will take you through four key areas where the impact of contaminated water can be catastrophic — whether measuring therapeutic levels of drugs in patient plasma samples or deciding to pass or fail a batch of API for drug formulation.

To find out more about the applications in these different areas, you can also [download our white papers on HPLC in pharma analysis](#) and [Reducing risk in HPLC/LC-MS therapeutic drug treatment and monitoring](#).

# Menu

**Pick an area,  
test your  
knowledge  
and learn...**

TEST YOUR KNOWLEDGE: THERAPEUTIC DRUG MONITORING

**Q**

**Which of these is the easiest method  
for therapeutic drug monitoring?**

**Q**

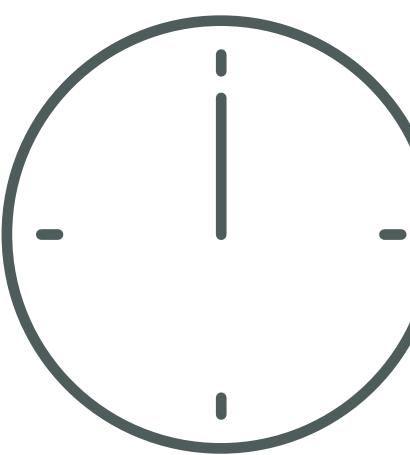
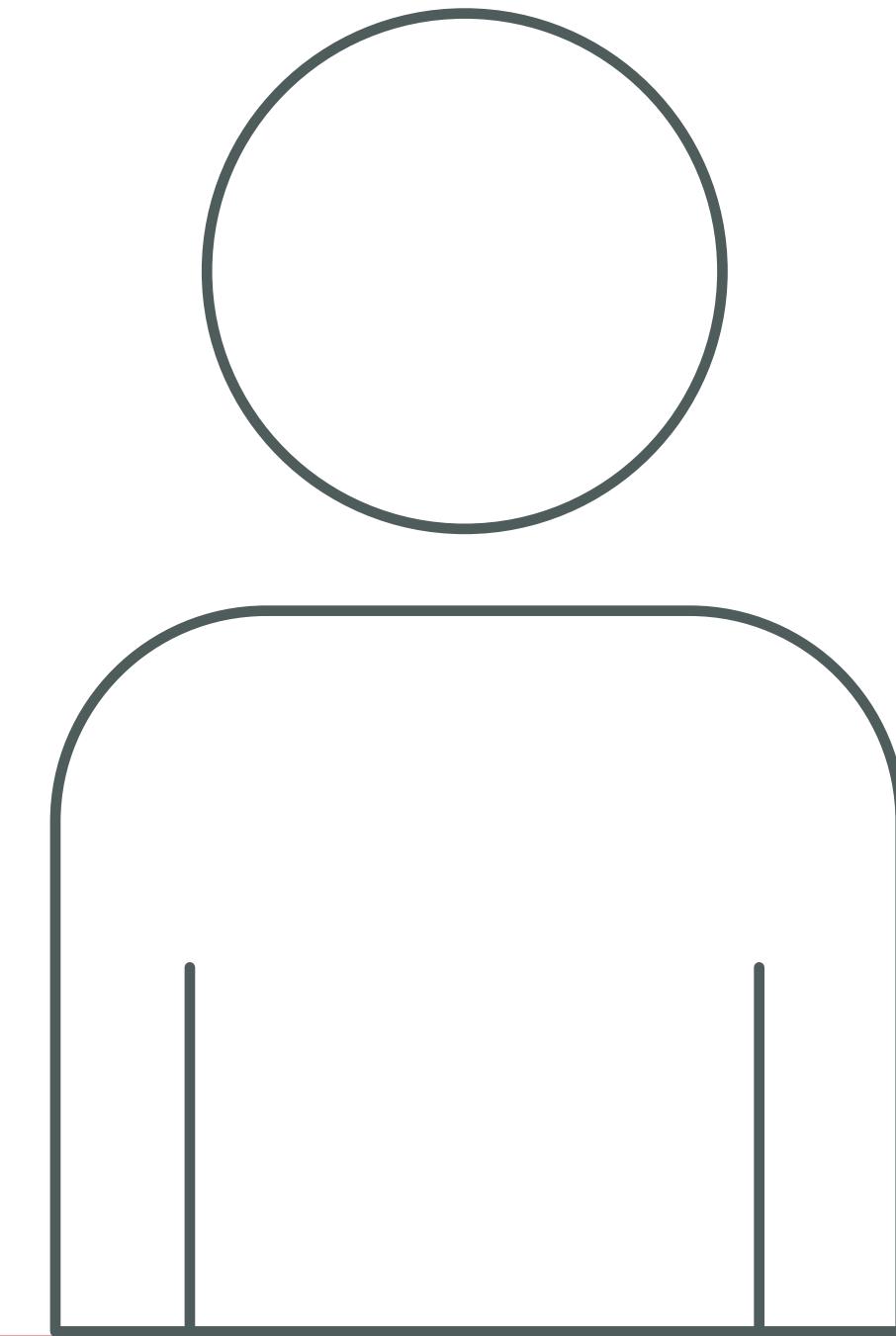
**Why is it so important to measure therapeutic drugs accurately?**

## EXPERIMENT 1

# Therapeutic drug monitoring

Therapeutic drug monitoring should be performed when the patient has achieved steady-state concentration, has changed drug therapy, or has had a change in response to treatment e.g. toxicity.<sup>2</sup>

Establish therapeutic ranges at timed blood collections after steady-state concentrations have been reached (generally 5-7 half-lives after initiation of or change in dosing).<sup>2</sup>



## RESULTS & IMPACT

# Therapeutic drug monitoring

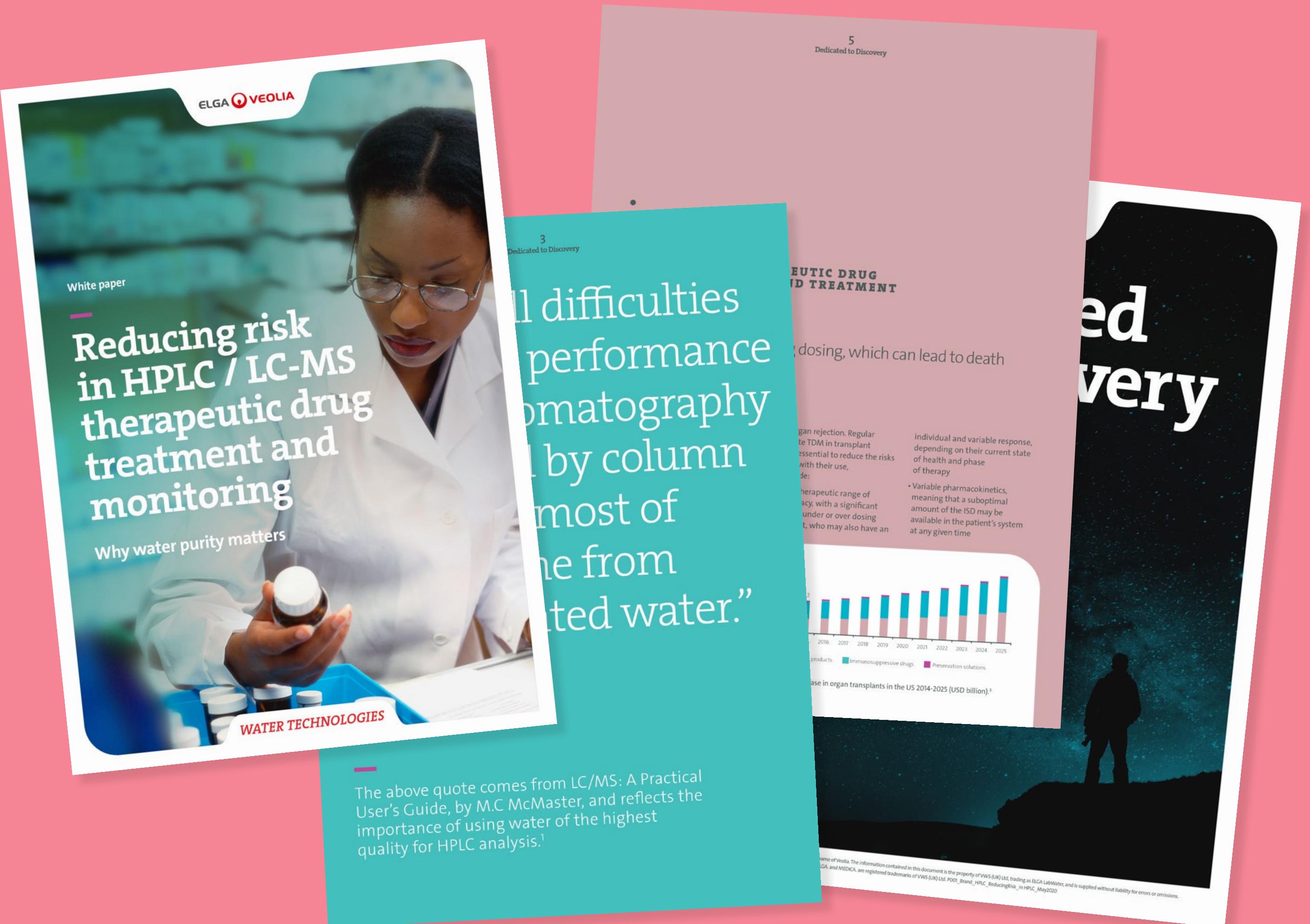
Results and impact on background with...

# DOWN LOADS

# Dive deeper...

LC-MS/MS is fast, flexible, adaptable, and allows the simultaneous quantification of multiple analytes. Discover more about the use of LC-MS for TDM and other applications in our white paper.

# Download whitepaper now



**TEST YOUR KNOWLEDGE: ACTIVE PHARMACEUTICAL INGREDIENT (API) MEASUREMENT**

**Q**

**What type of water is needed during pharmaceutical manufacture if the API is not sterile, but is intended for use in a sterile, parenteral product?<sup>4</sup>**

# Q

**Why is dissolution key in pharmaceutical analysis?**

## EXPERIMENT 2

# Active pharmaceutical ingredient (API) measurement

You need to avoid contamination that might affect the accuracy of your measurements if you are measuring the level of an API in a tablet during QA.

This is particularly important in the branded versus generics debate, where the vector substance that is carrying the active ingredient can have a key role in making the active ingredient available in the body.<sup>6</sup>

This can be measured via dissolution testing.<sup>7</sup>

## RESULTS & IMPACT

# Active pharmaceutical ingredient (API) measurement

Results and impact on background with...

## DOWNLOADS

# Dive deeper...

Discover in our white paper why ultrapure water – and choice of other types of water – is critical for HPLC applications in pharmaceutical manufacture.

**Download whitepaper now**

**White paper: HPLC in pharmaceutical analysis**

Why water purity matters

WATER TECHNOLOGIES

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**MANUFACTURE OF PHARMACEUTICAL INGREDIENTS AND**

at all stages in the synthesis

**Table 4**

| Manufacture  | Minimum acceptable quality of water |
|--|-------------------------------------|
| Coating  | Purified*                           |
| In formulation prior to non-sterile lyophilisation | Purified                            |
| In formulation prior to sterile lyophilisation     | WFI                                 |

**Table 5**

| Requirements                                 | Minimum acceptable quality of water   |
|--|---|
| Hypogency in API or the product will be used | Potable water*  |
| Hypogency in API or the product will be used | Potable water*  |
| Hypogency in API or the product will be used | Potable water**   |
| Hypogency in API or the product will be used | Potable water*  |
| use in a sterile, non-parenteral use         | Purified water  |
| parenteral use                               | Purified water  |
| use in a sterile, parenteral                 | Purified water with an endotoxin limit of 0.25EU/ml and control of specified organisms. |
|  | Water for injection   |

\*Water used during manufacture of medicinal products

\*\*The application would need to demonstrate that potential variations in the water extract

**“Guideline on the quality of water for pharmaceutical use” published by the European Medicines Agency on 13 November 2018**

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**ed very**

TEST YOUR KNOWLEDGE: FORENSIC TOXICOLOGY

Q

What is the most accurate type  
of sample to detect drug use?<sup>9</sup>



**Click to reveal more on the sample types commonly used to detect illicit drug use**

## EXPERIMENT 3

# Forensic toxicology

Establishing a person's exposure to drugs of abuse or pharmaceuticals is important for many situations including forensics, clinical applications or in doping control.

Drug analysis is usually carried out on body fluids, such as urine or blood samples. But in recent years, remarkable advances in sensitive analytical techniques has expanded opportunities for using drugs in less conventional samples, including hair.<sup>12</sup>

## RESULTS & IMPACT

# Forensic toxicology

Impact on results with

## DOWNLOADS

# Dive deeper...

Ultrapure water is key to accurate drug analysis of all sample types, whether dealing with doping in sport or drug-related crime. Find out more in our white paper.

[Download whitepaper now](#)

**White paper**

**Reducing risk in HPLC / LC-MS therapeutic drug treatment and monitoring**

Why water purity matters

**WATER TECHNOLOGIES**

**LC/MS: A Practical User's Guide**

The above quote comes from LC/MS: A Practical User's Guide, by M.C McMaster, and reflects the importance of using water of the highest quality for HPLC analysis.<sup>1</sup>

**Therapeutic drug treatment**

...ll difficulties in performance chromatography and by column most of the time from treated water."

...dosing, which can lead to death

...gan rejection. Regular TDM in transplant is essential to reduce the risks with their use, and:

- Variable pharmacokinetics, meaning that a suboptimal amount of the ISD may be available in the patient's system at any given time

...use in organ transplants in the US 2014-2025 (USD billion).<sup>2</sup>

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TEST YOUR KNOWLEDGE: WATER IN THE HOSPITAL ENVIRONMENT

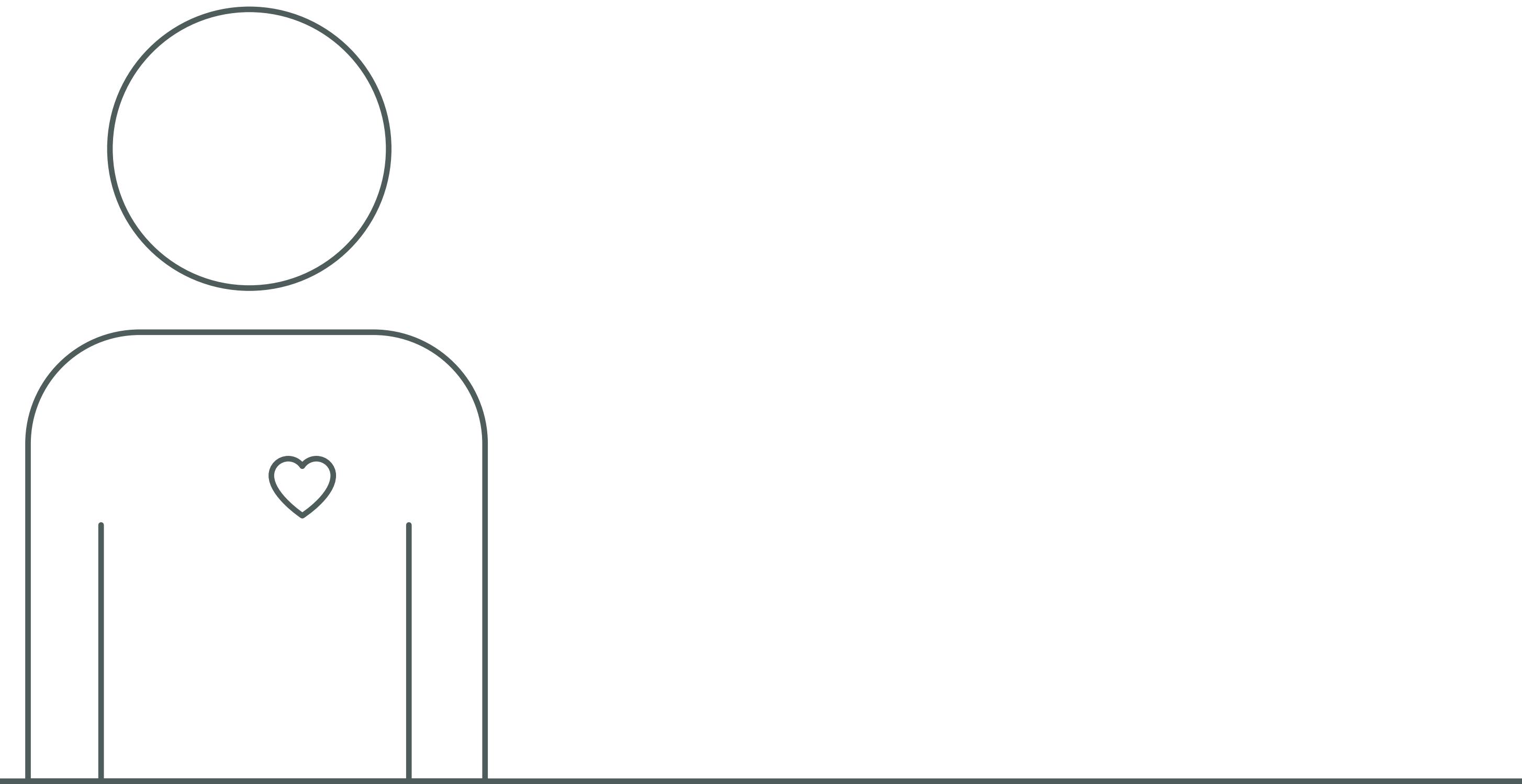
Q

**In which of these application areas does ultrapure water play a key role in the hospital environment?**

## TEST YOUR KNOWLEDGE: WATER IN THE HOSPITAL ENVIRONMENT

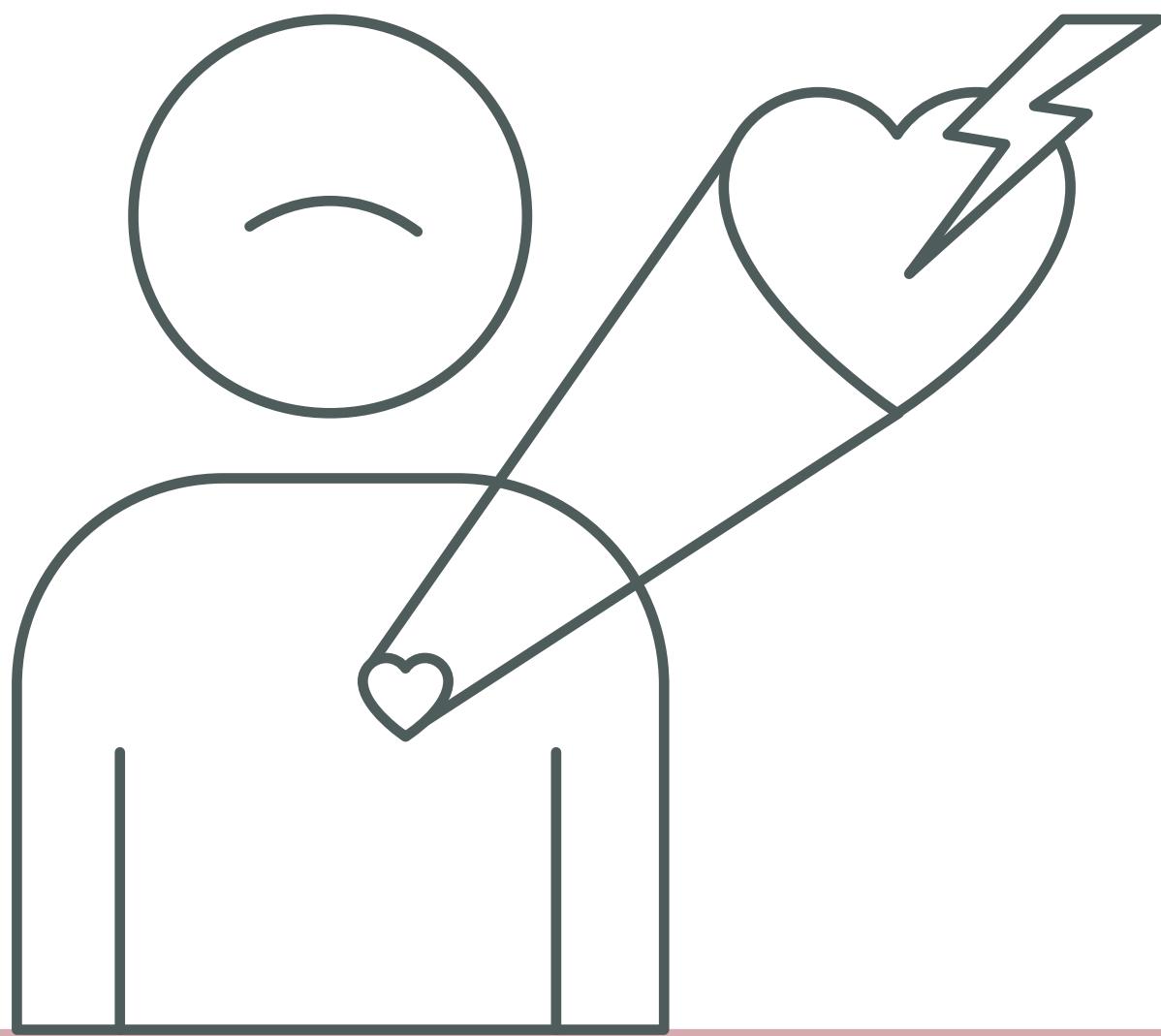
Here we imagine a scenario where a patient has suffered a heart attack, and we consider the role of water in the overall diagnosis and management of their condition.

**Click on the coloured icons to find out** the key areas where pure water plays a part in the care pathway of a heart attack patient



## HOSPITAL INSIGHT

# Heart patient scenario



Let's consider the role of water in the overall diagnosis and management of a heart patient's condition in more detail.

# DOWN LOADS

# Dive deeper...

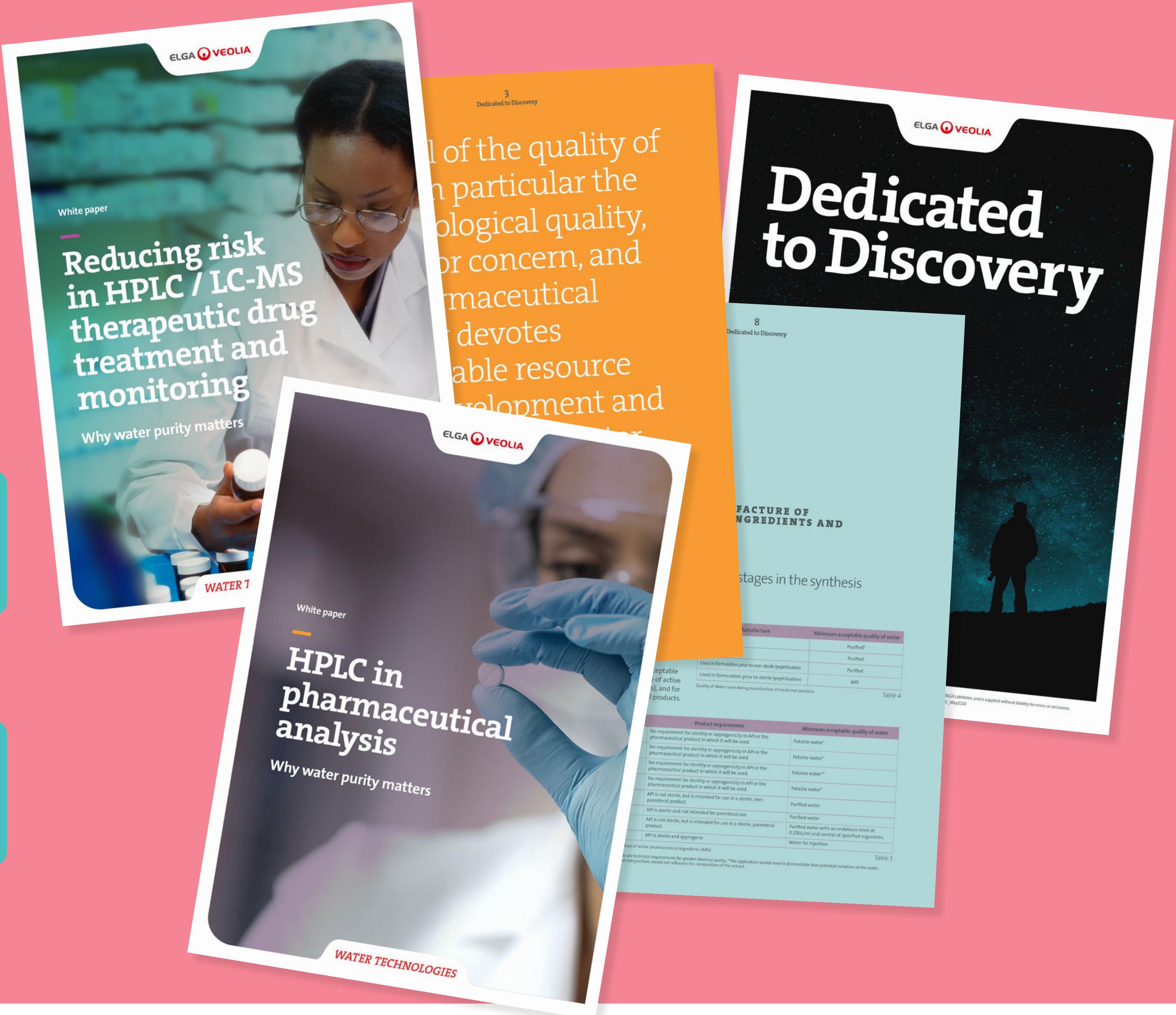
From analysis of patient samples after a heart attack to the precision medicine prescribed for recovery, ultra-water is key. Read more about the applications in our white papers.

# Water in LCMS applications

# Download whitepaper now

# Water in pharma applications

# Download whitepaper now



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