

Per- and poly- flouroalkyl substances (PFAS)

Navigating PFAS in Medical Devices

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About Battelle

World's largest non-profit R&D organization dedicated to applied science and technology since 1925



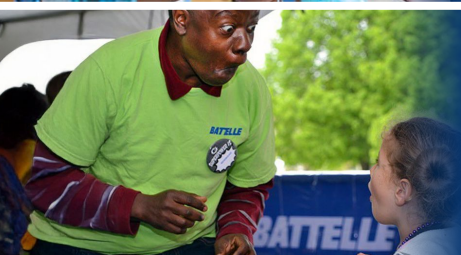
Applied Science & Technology

We're solving our customers' greatest challenges today while funding internal research to address tomorrow's threats.



STEM Education

We're bringing quality science, technology, engineering, and math (STEM) education to millions of students across the U.S.



Philanthropy

Our profits are reinvested not only in science and technology, but also in charitable causes.



Sustainability & Resilience

Doing what's right for the world

Our Mission Is To Translate Scientific Discovery And Technology Advances Into Societal Benefits

Our R&D activities span multiple sectors including Health, Environment, Infrastructure, National Security, and Laboratory Management resulting in nearly **\$10 billion in annual research and development spending** with Battelle.

National Security

Delivering mission-critical solutions in the air, on the ground, under water, and in cyber space.

Health

Innovating to accelerate discoveries that augment human health and performance, improving survivability, resilience, and recovery.

Environment & Infrastructure

Safeguarding assets, building dynamic research networks, and providing solutions to complex environmental challenges.

National Lab Management

Delivering scientific discovery and inspiring innovation with the management role we have in nine national laboratories.

Over 95 years of innovation

\$11B

Actual Revenue

2,700

Patents to Date

1,000+

Employees with Advanced Degrees

60

Locations, Globally

10

U.S. Locations HQ in Columbus, OH

1.4 M

STEM Students

\$20M

Annual Philanthropic Investment



PFAS

Leading the way in development of new solutions for PFAS-contaminated site restoration.



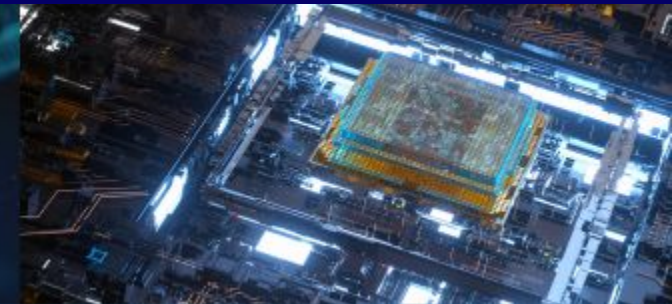
Neurotechnology

Pioneering ways to help overcome devastating neurological damage and disorders and restore movement.



Advanced Medicines

Bringing next-generation genomic medicines to market faster and accelerate novel medicines through the clinical pipeline.



Cyber Microelectronics Trust and Assurance

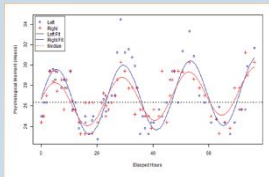
Leading technology development to protect critical systems from suspicious or malicious integrated circuits before they can become a threat.

Precision Health

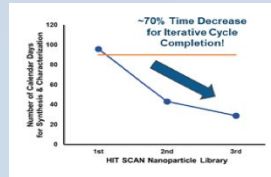
Medical Device Solutions

Health Research & Analytics

Capabilities



Measures for Sustaining Attention



Barcoded PNPs and HT-Discovery



New Product Development



Closed-Loop EMG Triggered FES



Biomedical Research



In Vitro Alternatives to Animal Models

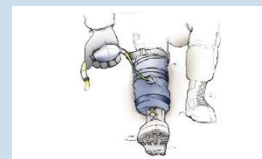
Innovations



Preventive Test for Cognitive Readiness for Duty



Genetic Medicine with Accelerated Delivery Vehicle



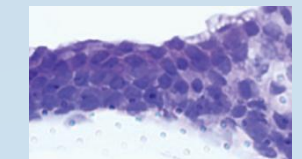
Limb & Wound Preservation



Accelerate Performance & Training, Prevent Injury, Recover Nervous System



Medical Countermeasures against Emerging Threats



Organ-on-a-Chip

Medical Device Solutions

65+

years of medical device design and development experience

250+

companies as their medical device research and development

100%

success rate for FDA submissions with Battelle human centric design work



Transformative Solutions

We bring together deep knowledge, world-class expertise, and specialized facilities to develop disruptive products that solve challenging problems

Comprehensive Medical Device Development

Human Centric Design

The right product at the right time, safely and effectively meeting your user's and client's needs.

Market Insights & Discovery

Every product ideation starts with an expert level of analysis and research, tailored with a scope on the industry.

Innovation

Our thought leaders guide you from concept to solution through design, development, testing, strategy, and more.

New Product Development

We take you to market entry with a well-defined, highly-organized product structure.

Post-launch Management

We help you solidify your product as an industry leading solution through continuous re-innovation.

A photograph of a person's hands pouring water from a faucet into a glass. The image is overlaid with a semi-transparent blue filter. The text 'PFAS Defined' is written in white on the left side of the image.

PFAS Defined

What are PFAS?

SURFACE TREATMENTS

Food-related

non-stick coated pans,
food wrappers and
containers



Household

stain-resistant fabric, carpet,
upholstery, leather protector,
hair care products, floor
polishes, air fresheners



Medical Devices

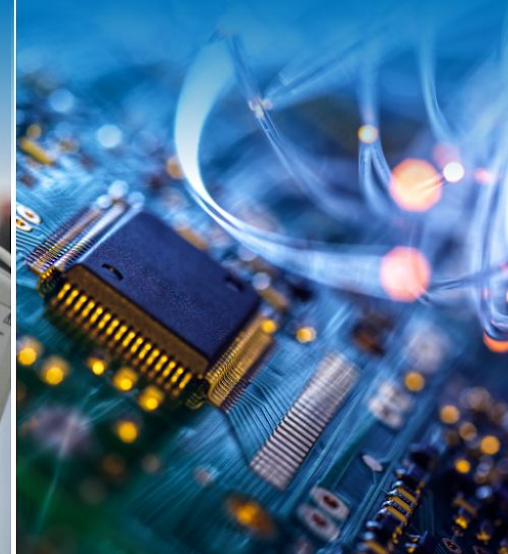
implants, surgical gloves,
catheters, tubing, blood bags,
needles, transdermal patches,
contact lenses, band aids,
wound bandages, diagnostic/
surgical equipment casing



PERFORMANCE CHEMICALS

Industrial

cabling materials, molds,
photolithography,
semiconductor, electronics,
building, construction, roofing



Automobile, AFFF

car paint, wiper blades, tires,
oil filters, lubricants, aqueous
film forming foams



Potential Adverse Health Effects

What matters in the context of the medical device industry?



Inconsistent regulation and standards (lack thereof)



Not all PFAS are created equal

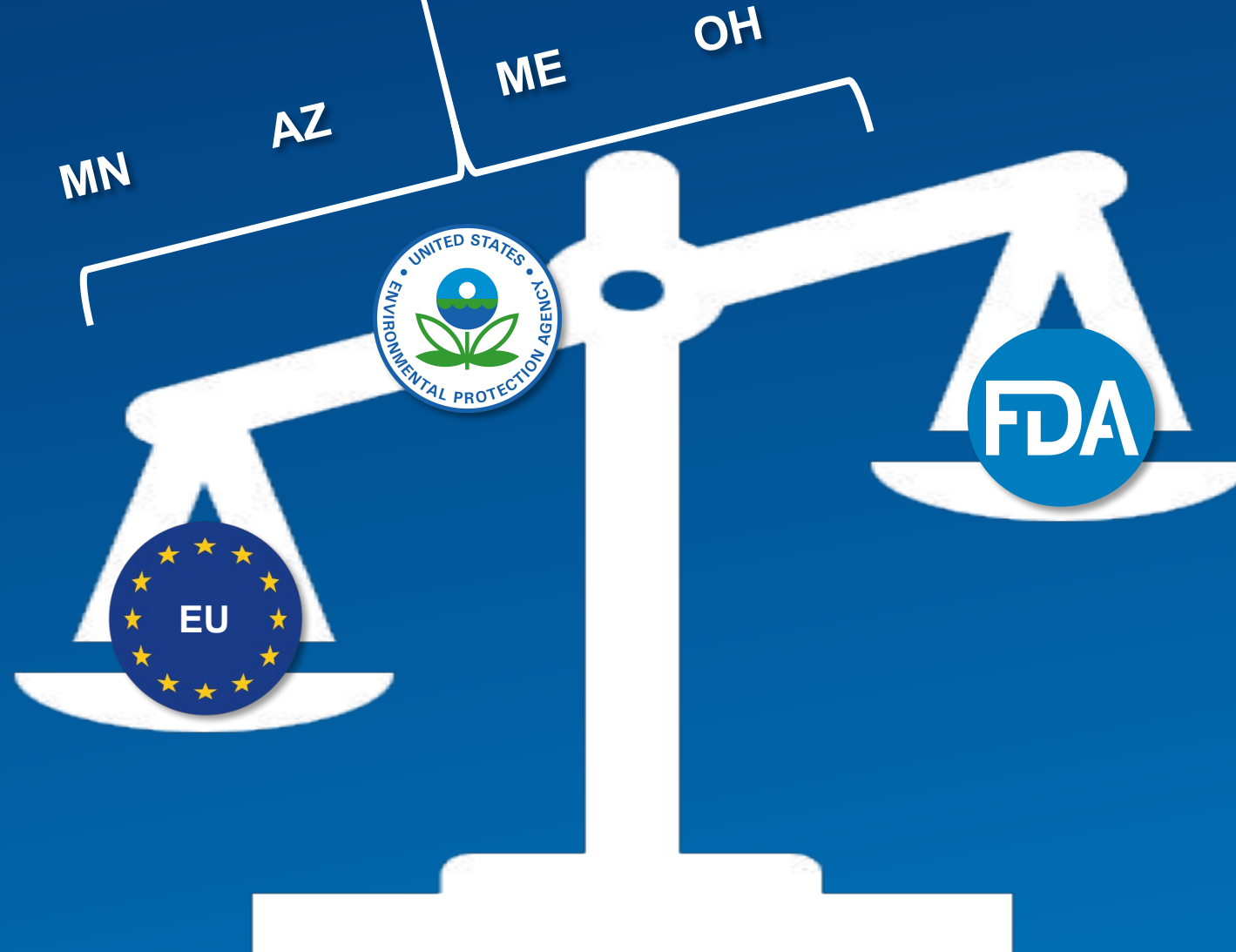


Risk= Hazard x Exposure

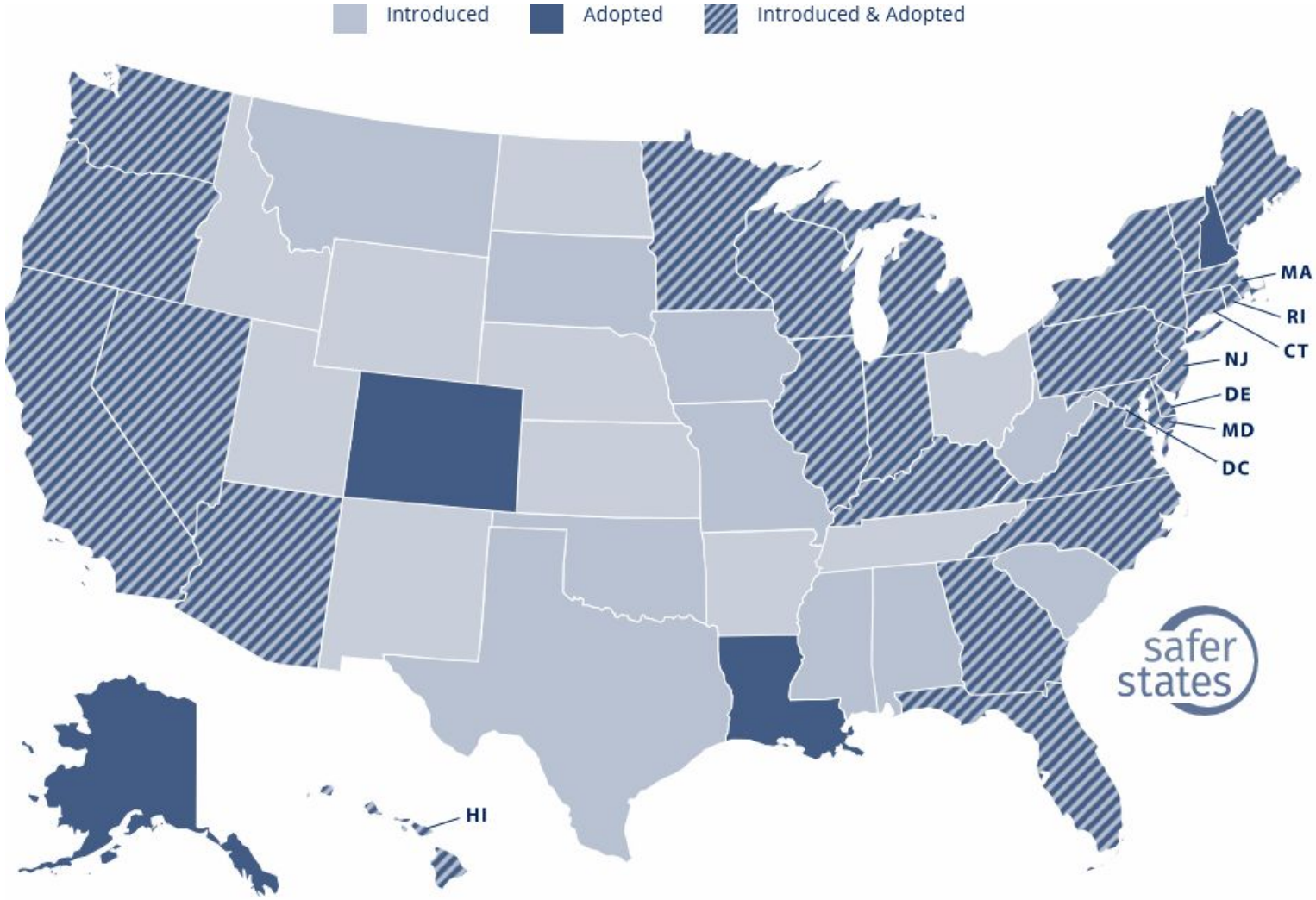


Regulatory Focus

Regulatory Update & Industry Impact



State Regulatory Map



State Regulatory Case Study

State	Status	Year	Bill	Toxic Chemical	Issue/Sector	Safer Solution	Description
Minnesota	Adopted	2021	SF 20	PFAS	Packaging	Accountability, Phasing Out the Bad, Setting The Stage	An omnibus bill allocates \$2.25 million for PFAS reduction, management, and drinking water protection, and bans food packaging with intentionally added PFAS starting January 1, 2024.
Minnesota	Introduced	2025	H.F.1621	PFAS	Packaging	Promoting Safer Solutions	Provides a one-time \$10 million grant to CelluComp for developing fiber-based packaging to reduce PFAS and plastics.
Minnesota	Introduced	2025	S.F.302	PFAS	Packaging	Promoting Safer Solutions	Allocates \$10 million for to the Department of Agriculture for a grant to develop sustainable packaging materials.
Minnesota	Introduced	2025	S.F.506	PFAS, Toxic Chemicals General	Water, Plastics, Microplastics	Setting The Stage	Appropriations bill funds PFAS projects, including prevention and treatment technologies, microplastic contamination solutions, PFAS tracking software, and biodegradation research.

EU Regulatory Landscape (ECHA & REACH)

April 2025

Consultations with competent authorities and stakeholders.

November 2025

Legislative proposal expected to be adopted and submitted.



REACH Revisions Timeline

July 2025

Completion of the Commission's impact assessment.

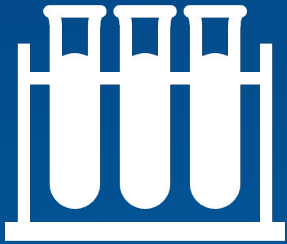
December 2025

Final 8-week public consultation period complete.

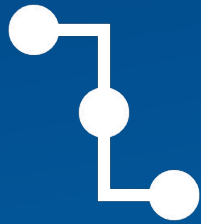


Industry Impact

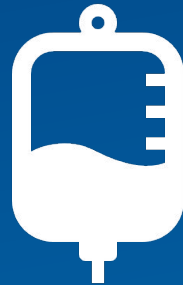
Industry Impact



Testing
challenges



Supply chain
disruption



Alternative
Materials needs



Industry Impact



FDA
resubmission
backlog



Manufacturing
redesigns



Patient facility
impact



Battelle PFAS Expertise



Developing Innovative Products within Health

2007

PFOS Human
Exposure Study

2010

PFOS/PFOA Navy
Environmental investigation

2016

Accredited PFAS
Lab Testing

2019

Fluorine-free
alternatives R&D

2024

Launch of comprehensive
PFAS lifecycle services

PATH TO PFAS FREE

2009

PFOS Human
Cancer Studies

2014

First PFAS Remedial
Investigation

2018-22

Over \$8M Internal R&D
Investment

2023

Technology Commercialization
for PFAS treatment and destruction

Our Solutions



Key Takeaways for Medical Device Stakeholders



Stay Informed



Engage supply chains

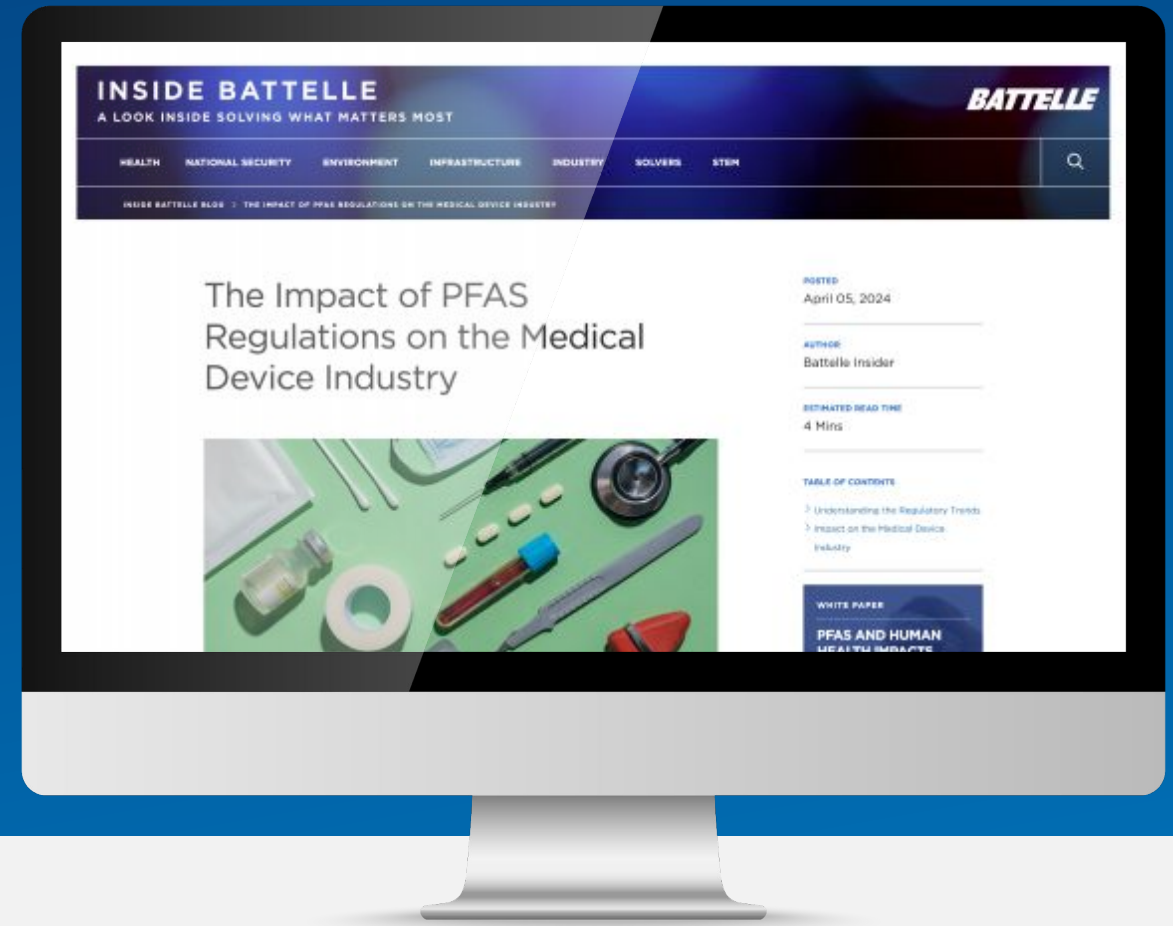


Proactively Manage Risk



Knowledge Center

- PFAS Website
- FAQ's
- Marketing Brochure
- Featured Blogs & Articles
- Upcoming Webinars & Conferences



Appendix

Knowledge Center

Blogs & Articles

- [The Impact of Regulations on the Medical Device Industry](#)
- [Phasing Out “Forever Chemicals”: Finding Alternatives for PFAS \(battelle.org\)](#)
- [PFAS and Human Health](#)

FAQs

- (need link)

Marketing Brochure

- Navigating PFAS In Medical Devices (need link)

Press Release

- Battelle Prepares to Guide Medical Device Companies Through New Federal, State and International Regulations on “Forever Chemicals (need link)

New PFAS Web Pages

- [PFAS and Emerging Chemicals](#)
- [PFAS Product Stewardship and Safety](#)
- [PFAS Testing and Analysis](#)
- [PFAS Assessment and Investigation](#)
- [PFAS Destruction and Remediation](#)

BATTELLE

It can be done

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