SUSTAINABILITY WORKSHOP

QP Forum. 13th May 2025

Catherine Mulhall & Michael Kilkelly

AGENDA

- Welcome (10 mins)
- Sustainability & Compliance (20 mins)
- Case Studies: Sustainability in Quality Systems (45 mins)
- Action Planning (10 mins)
- Reflection & Wrap Up (5 mins)

INTRODUCTION



Brendan Griffin Professor, University College Cork



Michael Kilkelly Senior Executive EHS Biopharmachem Ireland (IBEC)



Catherine Mulhall Pharmacist & Sustainability Expert

WHAT DOES **SUSTAINABILITY MEAN IN** QUALITY **ASSURANCE &** QUALIFIED **PERSON ROLES?**



Mentimeter. https://www.menti.com

Code: 2685 5931

LONG-TERM TEMPERATURE GOAL OF THE PARIS AGREEMENT NOT YET DEAD BUT IN GRAVE DANGER.

Moral Imperative

- Essential ingredients of good <u>health</u> – clean air, safe drinking water, nutritious food supply and safe shelter <u>under threat.</u>
- Last 10 years are the warmest years on record.
- **~70% drop** in mammal, bird, fish, reptile, and amphibian populations since 1970.



WHICH OF THESE DO YOU THINK HAS THE BIGGEST SUSTAINABILITY IMPACT IN MEDICINAL PRODUCTS?

A. Packaging
B. Excipients
C. API's
D. Manufacturing Process
E. Distribution
F. Use
G. It Depends

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EVOLVING SUSTAINABILITY REGULATORY LANDSCAPE

Directive	Purpose	Scope
Green Claims Directive	To combat greenwashing Environmental claims must be accurate, verifiable, and scientific evidence.	All businesses operating in the EU that make voluntary environmental claims on product or company. -substantiation using recognized life cycle methodologies (like LCA). - Independently verified
Corporate Sustainability Reporting Directive (CSRD)	To improve the quality, consistency, and comparability of sustainability information disclosed by companies	Mandatory for >1,000 employees and >50 million turnover Voluntary if below these thresholds.
Corporate Sustainability Due Diligence Directive (CSDDD)	To identify, prevent, and mitigate adverse human rights and environmental impacts across companies' value chain.	Tier One suppliers

LIFE CYCLE ASSESSMENTS ARE KEY STARTING POINT TO UNDERSTAND PRODUCT'S ENVIRONMENTAL FOOTPRINT



Multi Indicators including;

- Climate Change
- Water
- Biodiversity
- Land Use
- Eutrophication
- Acidification
- Ozone Depletion
- Human Toxicity
- Ecotoxicity

Product Environmental Footprint is the life cycle assessment methodology recommended by the EU.





Carbon footprint of oral medicines using hybrid life cycle assessment

Max Piffoux ^{a b}, Antoine Le Tellier ^c, Zoé Taillemite ^c, Coline Ducrot ^d, Sébastien Taillemite ^c $\stackrel{<}{\sim}$ 🖾

Show more \checkmark

Method:

Estimate the cradle-to-pharmacy gate Lifecycle assessment of all oral medicines from the French pharmacopeia (n = 12,316 medicines)

Key Findings:



- Low-cost medicines have significantly higher emission factors (0.2–0.3 kgCO₂/€ versus 0.05–0.1 kgCO₂/€ for highcost drugs.)
- Orphan & innovative medicines tend to have higher carbon footprints.

WORKSHOP ONE CLEAN ROOMS

'HOW MUCH DOES YOUR BUILDING WEIGH, MR.FOSTER?'

HOW MUCH ENERGY DOES YOUR CLEAN ROOM CONSUME?

TYPICAL ENERGY USE DISTRIBUTION IN A PHARMA PLANT





Reducing carbon footprint

Energy Source

Energy reduction

Radical Approach

Energy Source

540 GwH of Electricity demand

70 GwH produced by on site renewables

300 GwH sourced from renewables on the grid



ENERGY REDUCTION

Heat recovery

Air recycling

Challenge air changes

CleanRoom Class	ISO Class	Required Air change per hour
Class 100	ISO 5	240-480
Class 1000	ISO 6	150-240
Class 10,000	ISO 7	60-90
Class 100,000	ISO 8	5-48

HOW WOULD YOU APPROACH A REDUCTION IN AIR CHANGES? 10 MINS



CHALLENGING AIR CHANGES

• To apply HVAC airflow optimization safely in a cleanroom, consider:

• Regulatory compliance: Focus on particle control, pressure differentials, and recovery times, not ACH alone.

• Occupancy patterns: Use ARM when no personnel are present, but maintain room classification.

• Risk assessment and validation: Critical to ensure cleanliness and control parameters remain within specification.



Radical Approach

WHY ARE THERE HUMANS IN CLEAN ROOMS, MR.FOSTER'

WORKSHOP TWO: HAZARDOUS WASTE

Responsible Care Aggregated data from 48 Pharma/biopharma companies



57 % of hazardous waste is treated outside Ireland A significant portion is solvent Pollution is nothing but the resources we are not harvesting. We allow them to disperse because we've been ignorant of their value.

BUCKMINSTER FULLER

GMP SOLVENT RECOVERY: A PROPOSITION

What are the opportunities & risks from a QP perspective?

CONCLUSION