Sustainability in the life-sciences industry

Nic van der Nol

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Regulatory Knowledge, Practically Applied.

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Sustainability in context

"Europe Ushers in a New Bauhaus Era of Sustainability" [1]

- Founded the "Bauhaus movement" in 1919 by Walter Gropius in Weimar, Germany
- Paradigm shift in era of change and disillusionment (WWI)
- Embrace of modern technologies in order to succeed in a modern environment
- The most basic tenet of the Bauhaus was form follows function
- Sustainable approach to building design and construction

1 Ursula von der Leyen, President of the EU Commission, announces the New European Bauhaus initiative to promote a more sustainable and affordable architectural future in the EU. October 2020.

The S-word – What is Sustainability?

- **1963:** "*Scarcity and Growth*" (Barnett and Morse) – generally recognised as the earliest formal articulation of sustainability and concerns about the environment.

- **1970s-1980s:** The World Conservation Strategy (WCS): integrating economic and environmental management. Unsuccessful in conveying the relationship between economic policy and environmental degradation.

- **1983:** The United Nations the Brundtland Commission: investigates inter-relationship between human activity and the environment and implications for economic and environmental policy.

- **1987:** Brundtland Report "*Our Common Future*" World Commission on Environment and Development (WCED) - successfully established sustainability as a critical part of economic development policy.[1]

- **2015:** All United Nations Member States adopt the United Nations Sustainable Development Goals (UN SDGs)[23] within the 2030 Agenda for Sustainable Development.

1 The Principles and Practice of Sustainable Economic Development Majah-Leah V. Ravago,... Ujjayant Chakravorty, in Sustainable Economic Development, 2015

Sustainability: Regulations and Risks

- Limited regulatory demands or requirements: No PIC/s requirements, although sustainability could generally regarded as a measure of **continuous improvement**
- GMP position purely focussed on our responsibility to prove the measures we decide to deploy are effective - don't compromise safety, purity and quality of products
- Unsurprisingly - generally risks found to be inversely proportional to the proximity to the most critical processes:
  - Sterile products HVAC systems
    - Highest profile due to potential adverse impact on critical cleanroom performance and cleanliness attributes.
  - OSD HVAC systems
  - Critical utilities
  - Secondary packaging HVAC systems

International Organization for Standardization (ISO) on Sustainability

- Sustainability: the goal of sustainable development[1]
- Sustainability:

  "…any state of the global system in which the needs of the present are met without compromising the ability of future generations to meet their own needs…" (Brundtland)

- Sustainable development: development that leads to sustainability
- Social responsibility: how an individual organization can contribute to sustainable development
- ISO standards impact on the achievement of sustainability, either directly (where they specifically address sustainability issues) or indirectly (e.g. where they relate to testing, products, procedures, services, terminology, management systems or auditing)

Update of ISO Technical Committee 209 Cleanrooms and Associated Controlled Environments, Journal of the IEST, V. 64, No. 1 © 2021
David S. Ensor, Past Chair ISO/TC 209; Robert Mielke, Committee Manager, ISO/TC 209, IEST Fellow; Jennifer Sklena, Manager, Technical Programs, Institute of Environmental Sciences and Technology (Working Group 11, WG11)
http://meridian.allenpress.com/jiest/article-pdf/64/1/57/2990242/i1557-2196-64-1-57.pdf (02 May 2022)
1. ISO Guide 82, Guidelines for addressing sustainability in standards https://www.iso.org/standard/76561.html

International Organization for Standardization (ISO) on Sustainability in Cleanrooms

"ISO now stresses development of standards with requirements to support sustainability supporting a United Nations initiative.[1] Cleanrooms and associated controlled environments are very resource intensive facilities.

The recently published standard on energy management in cleanrooms **(ISO 14644–16:2019)** [sic] supports that need. The better management of the energy required by cleanrooms reduces broader energy requirements and operating costs.

The direction of WG11 to develop guidance with respect procurement of consumables may also affect sustainability. There may be other opportunities in the future to address sustainability." [2]

1. ISO Guide 82, Guidelines for addressing sustainability in standards https://www.iso.org/standard/76561.html
2. Update of ISO Technical Committee 209 Cleanrooms and Associated Controlled Environments, Journal of the IEST, V. 64, No. 1 © 2021 David S. Ensor, Past Chair ISO/TC 209; Robert Mielke, Committee Manager, ISO/TC 209, IEST Fellow; Jennifer Sklena, Manager, Technical Programs, Institute of Environmental Sciences and Technology (Working Group 11, WG11) http://meridian.allenpress.com/jiest/article-pdf/64/1/57/2990242/i1557-2196-64-1-57.pdf (02 May 2022)

ISPE Handbook: Sustainability

Principles and Policy:

- Sustainability in the Context of the Life Sciences Industry
- Legislation, Regulation, Sustainable Policy Development
- Sustainability Assessment for Buildings and Products
- Future Directions and Opportunities

Design/Engineering application:

- Process Development and Bulk Drugs Manufacture
- Formulation and Packaged Drug Product Manufacture and Logistics
- Pharmaceutical and Biopharmaceutical Manufacturing Supply Chain
- Site and Facility Design Considerations
- Energy, HVAC, Electricity, Utilities, Waste Management

www.ISPE.org 2015

Sustainability – Trajectories

- The proposed NCC changes later this year will shift to 7-star ratings for homes, the focus will likely shift to commercial sector for the next version:

  "More substantial changes for commercial buildings may be considered in NCC 2025. This may involve the same approach used for residential buildings in NCC 2022, i.e. the development of two possible options with one being net zero." [1]

- Likely to see increased requirements for commercial building, and the NCC already has provision for Greenstar solutions, for example Section J compliance:

  "Building rating systems such as Green Star and the National Australian Built Environment Rating System (NABERS), as well as mandatory disclosure under the Commercial Building Disclosure Program, have been effective in motivating owners of commercial buildings to make energy efficiency improvements." [2]

- There is also evidence of general policy trends shifting towards energy efficient, certified buildings. COAG has a plan, to drive net zero energy and carbon buildings by 2030, which will be expressed through regular updates to the NCC.

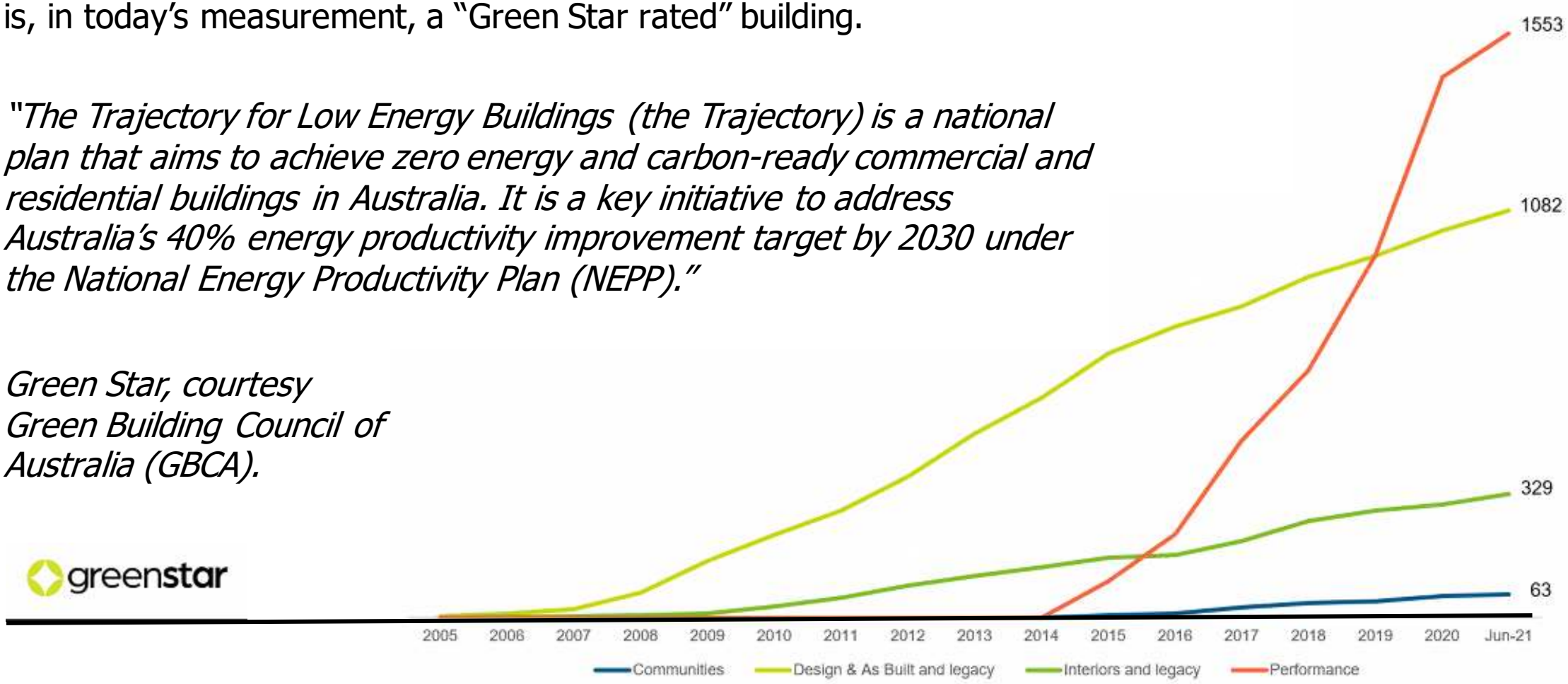
1 ABCB 2019 Outcomes report: "Energy efficiency and beyond"
2 ABCB 2022 Outcomes report: "Energy efficiency and beyond"

Sustainability – Trajectories

Likely to see buildings (built under NCC 2025 onwards) requiring what is, in today's measurement, a "Green Star rated" building.

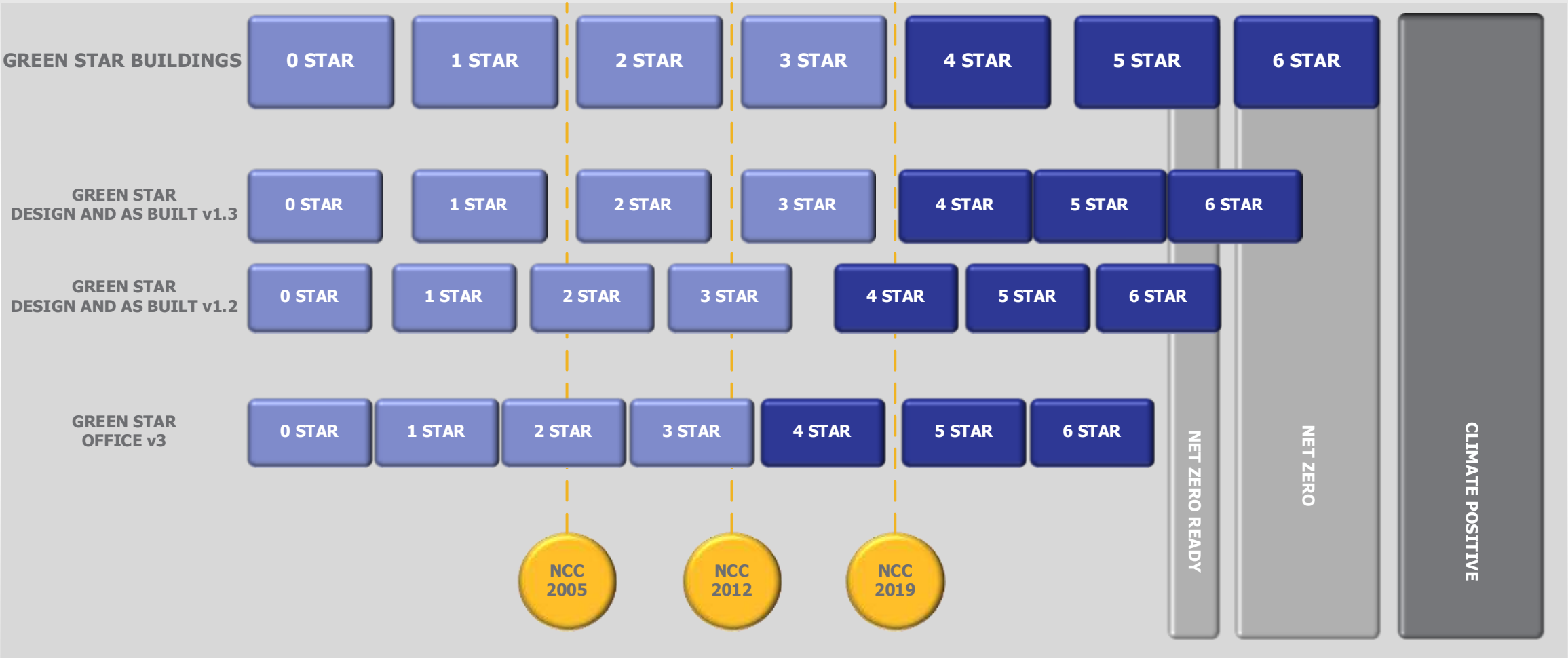
"The Trajectory for Low Energy Buildings (the Trajectory) is a national plan that aims to achieve zero energy and carbon-ready commercial and residential buildings in Australia. It is a key initiative to address Australia's 40% energy productivity improvement target by 2030 under the National Energy Productivity Plan (NEPP)."

Green Star, courtesy Green Building Council of Australia (GBCA).



Sustainability – Trajectories

New target of net zero emissions for new buildings and fitouts



Green Star, courtesy Green Building Council of Australia (GBCA).

GREEN STAR
Credits[1]

RESPONSIBLE 17%
- Industry development
- Responsible construction
- Verification and handover
- Responsible procurement
- Responsible structure
- Responsible envelope
- Responsible systems
- Responsible finishes

POSITIVE 30%
- Upfront carbon emissions
- Energy use
- Energy source
- Other carbon emissions
- Water use
- Life cycle impacts

NATURE 14%
- Impacts to nature
- Biodiversity enhancements
- Nature connectivity
- Nature stewardship
- Waterway protection

RESILIENT 9%
- Climate change resilience
- Operations resilience
- Community resilience
- Heat resilience
- Grid resilience

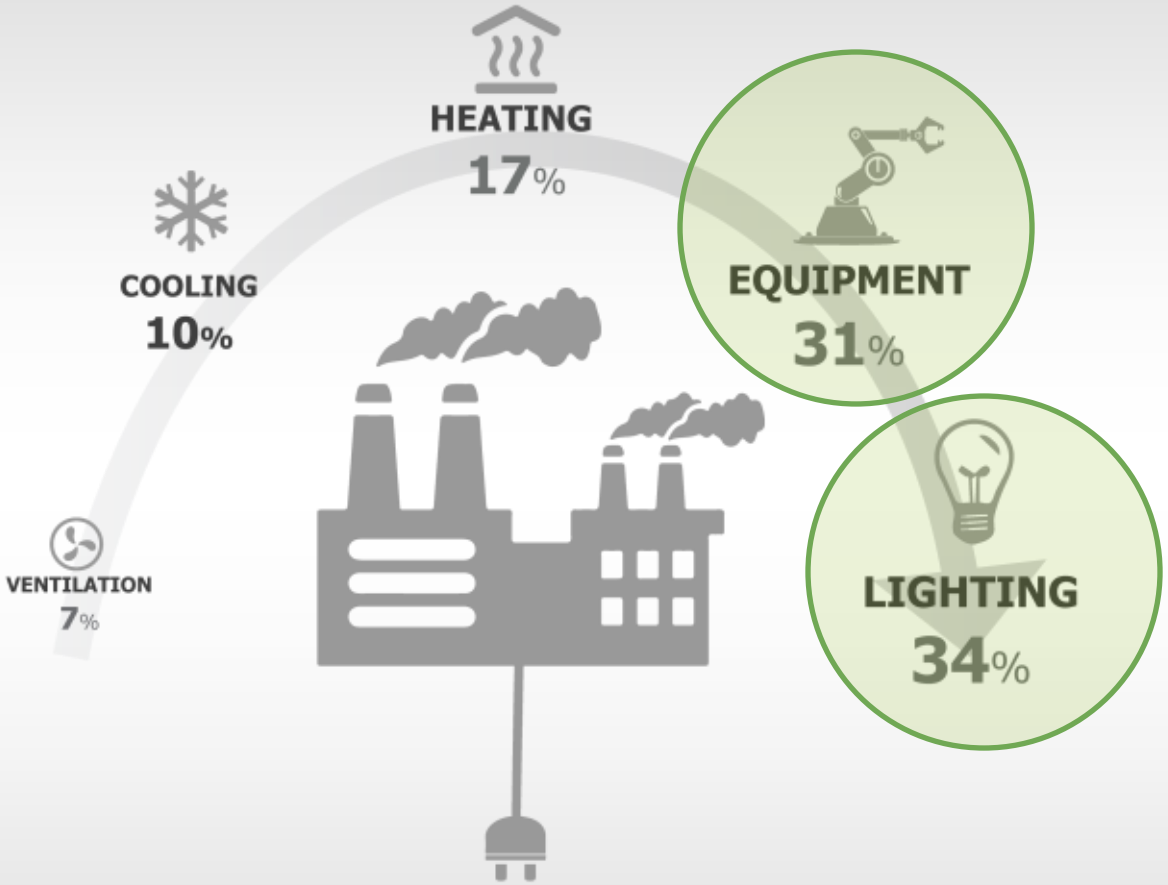
PLACES 8%
- Movement and place
- Enjoyable places
- Contribution to place
- Culture and heritage

HEALTHY 14%
- Clean air
- Light quality
- Acoustic comfort
- Exposure to toxins
- Amenity and comfort
- Connection to nature

PEOPLE 8%
- Inclusive construction practices
- Indigenous inclusion
- Procurement and workforce inclusion
- Design for inclusion

[1] Green Star Buildings rating tool

GREEN STAR
Energy Usage Focus



TOTAL ELECTRICITY USE

300 kWh/sqm

Typical manufacturing facility

Approximate figures only

Focus on Green Star building category 'POSITIVE' of energy efficiency and Indoor Environment Quality, the largest (typical) consumers of energy in facilities to target a **30% reduction in energy usage.**

EFFICIENT LIGHTING

MACHINE EFFICIENCY

PASSIVE SOLAR DESIGN

50-80% of site energy is used in HVAC

(Heating, Ventilation and Air Conditioning)

Pfizer Inc reported over $250,000,000 per year [1]

[1] ISPE Brussels HVAC 2009

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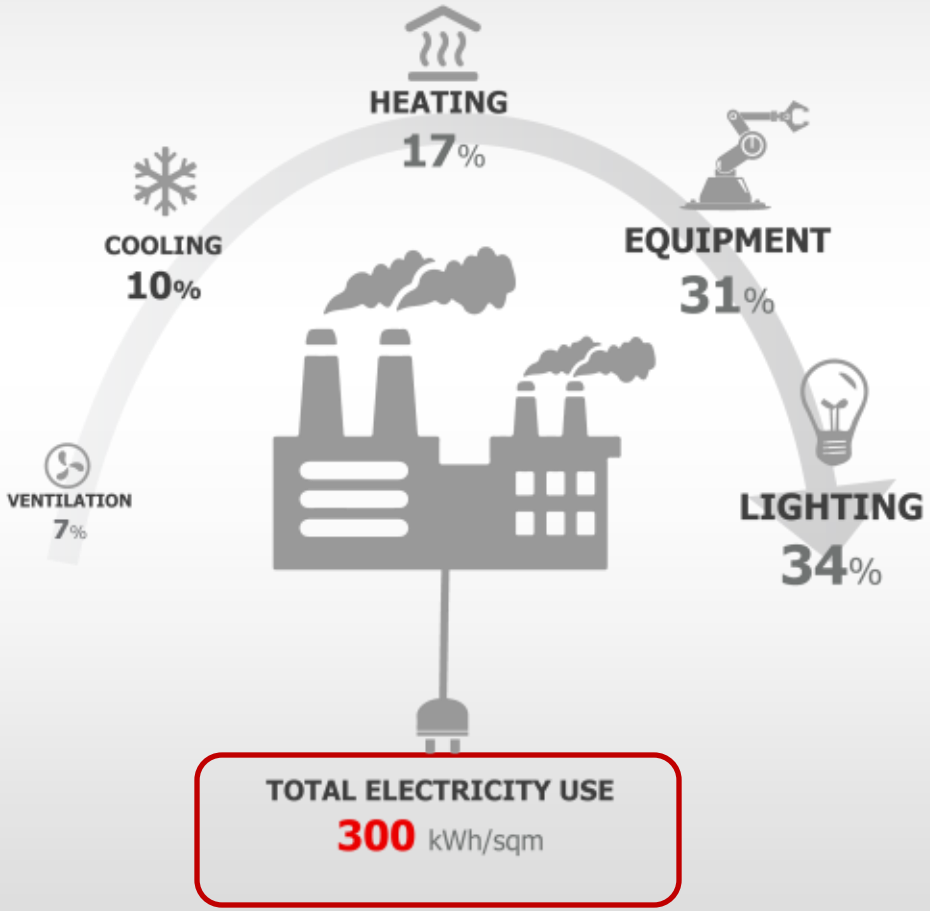
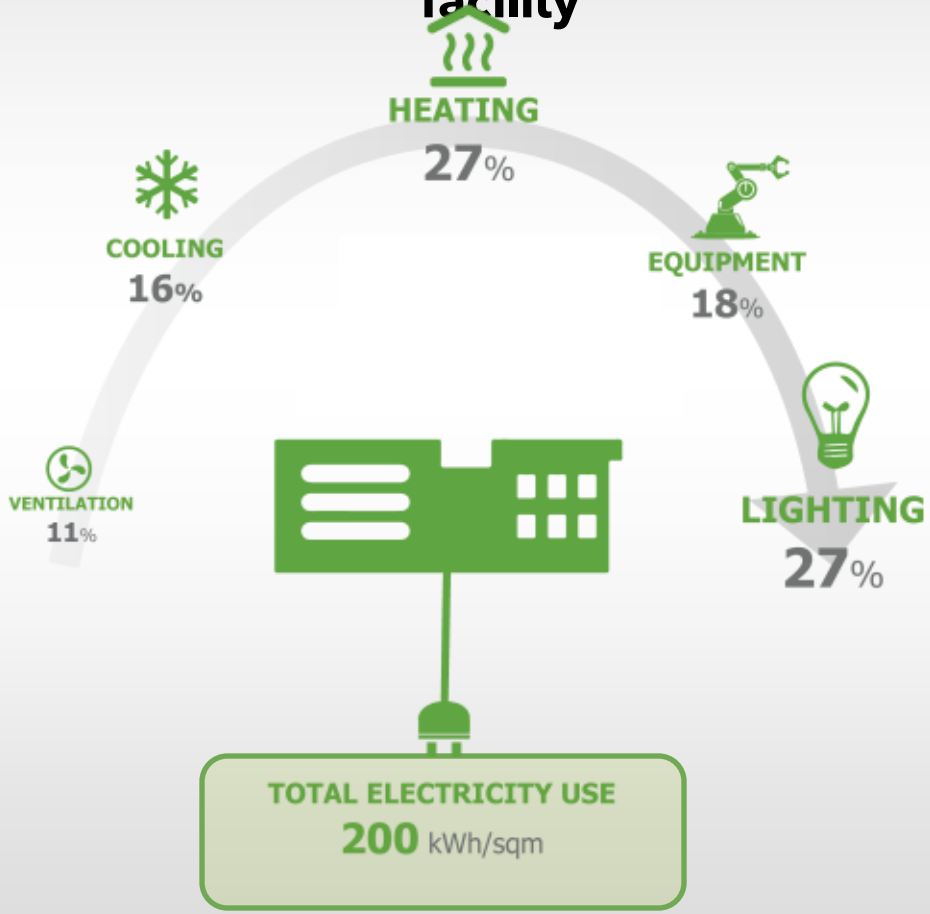
GREEN STAR
Energy Usage Focus

The typical manufacturing facility



The emerging manufacturing facility



Approximate figures only

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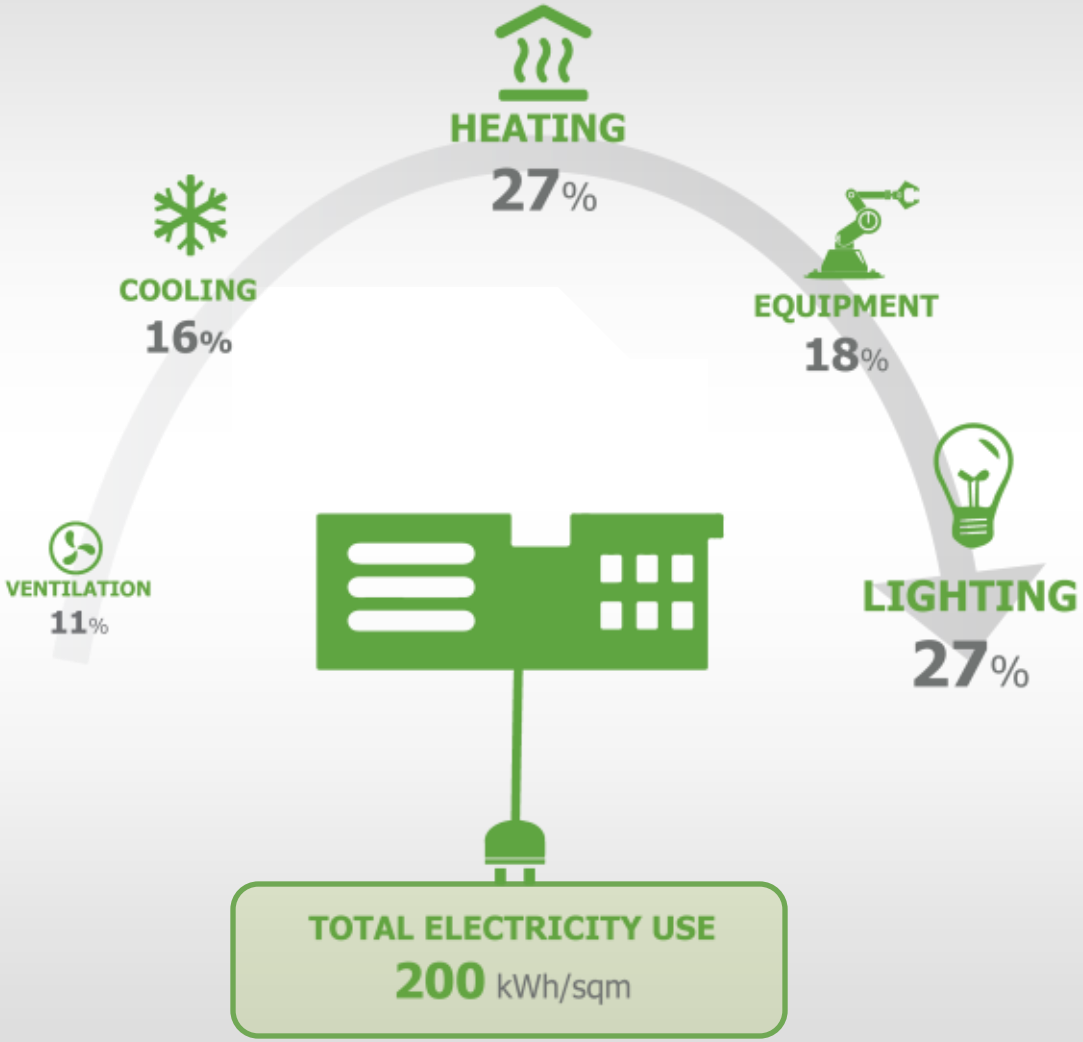
GREEN STAR
Energy Reduction Techniques

Techniques

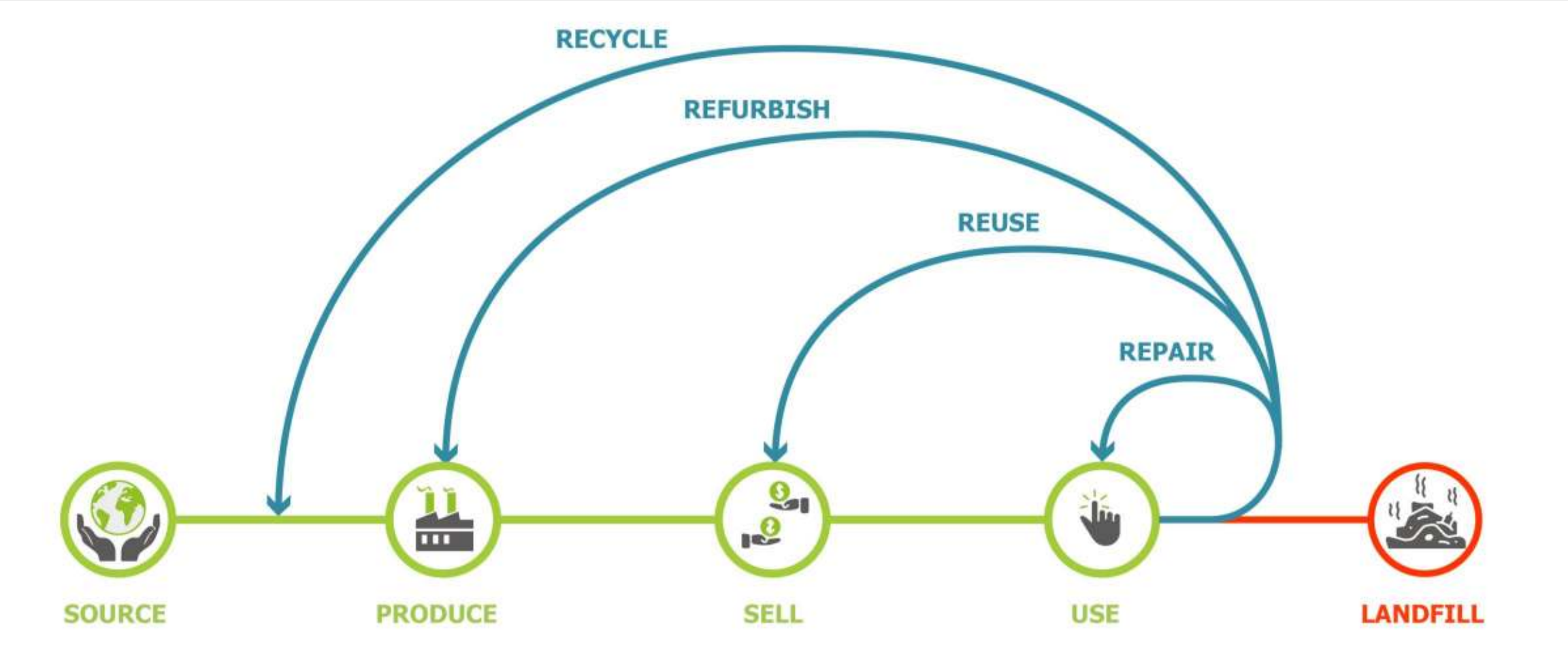
- LED high efficiency lighting
- Intelligent lighting
- Passive solar design
- Borrowed lighting
- Automation
- Dark warehouses



Approximate figures only

GREEN STAR

Context of a "Circular Economy"



GREEN STAR
Lighting Techniques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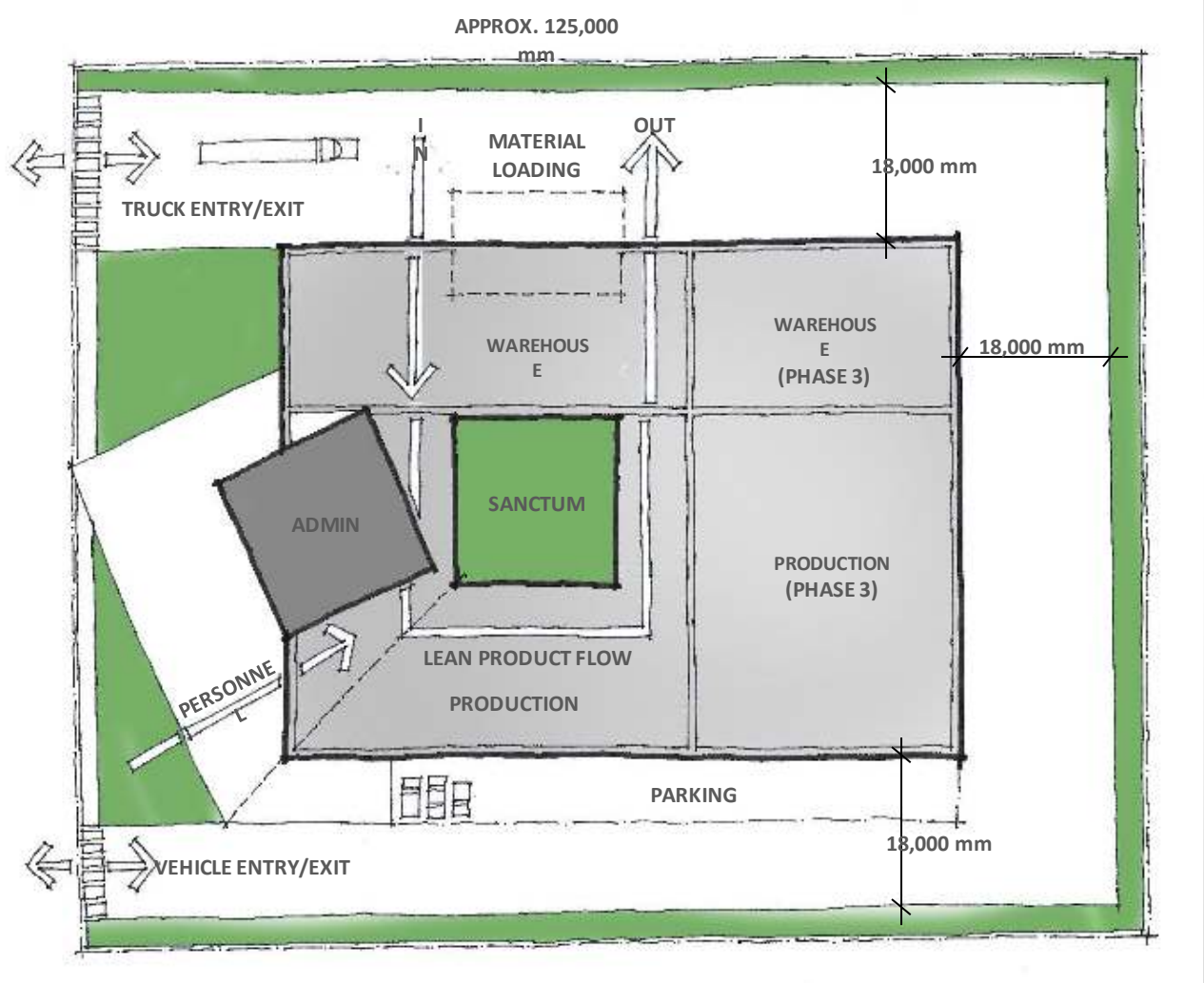
Artist Impression

Designing through "bio-immersion"



The facility concept provides a central green courtyard, with process wrapped around.

Circulation and offices spaces are to have direct views to planted areas, which will provide natural lighting phytoremediation to rainwater.

Rainwater will be filtered/stored and re-used in this planted space before being discharged to the environment.

Immersing healthy workplaces within a green open space is used to boost morale and productivity.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Artist Impression


PharmOut
Artist impression

Environmental Impact Reduction

ISPE FOYA Example of execution of sustainability in practice

2022 Category Winner Project Execution
Janssen Biologics, BV
Project: Vaccine Launch Facility (VLF) Expansion Leiden, The Netherlands

- Water efficiency
- HVAC energy recovery
- LED lighting (and associated energy saving controls)
- Low-emitting materials in building construction
- Upskilling existing employees enabling increase of manufacturing output
- innovative technological and manufacturing platforms

Environmental Impact Reduction

ISPE FOYA Example of execution of sustainability in practice

2018 Category Winner Sustainability
Wyeth Pharmaceuticals Co, a Pfizer Company
Project: Project Diamond, Suzhou, Jiangsu Province, China

- Certified LEED (Platinum)
- Solar power generation with photo-voltaic cells, EV charging station
- Solar heating for DHW, solar and wind power lighting (for outdoor areas)
- Rainwater harvest system
- Recycling 100% of treated wastewater for cooling tower makeup, toilets and lawn
- Heat recovery of HVAC and compressors
- Zero nitrogen and phosphorous in wastewater discharge (to protect one of the largest freshwater lakes nearby)
- Green roof, green wall, reflective road and roof surfaces
- Increased natural light in building design
- Provision of electric sun shading

Environmental Impact Reduction
Examples

Photovoltaic Cells

Target 600 tonne per year saved.

Reduced draw on grid at peak

- Proposed 750kw system
- Battery storage

Cross Laminated Timber

Substantial reduction in embodied carbon vs traditional reinforced concrete.

Timber manufacture releases 625% less CO2/kg compared to concrete and overall as a material has a net positive effect.

- 30% reduced build time
- 20% reduced weight
- Elimination of high risk site activities
- Advantageous thermal performance

Stormwater harvesting

Target 1.75 ML per year saved

Target 50% of total consumption provided.

- Tree pits
- Rainwater harvesting
- Indigenous Xerophytic planting
- Stormwater runoff bio-remediation.

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Environmental Impact Reduction

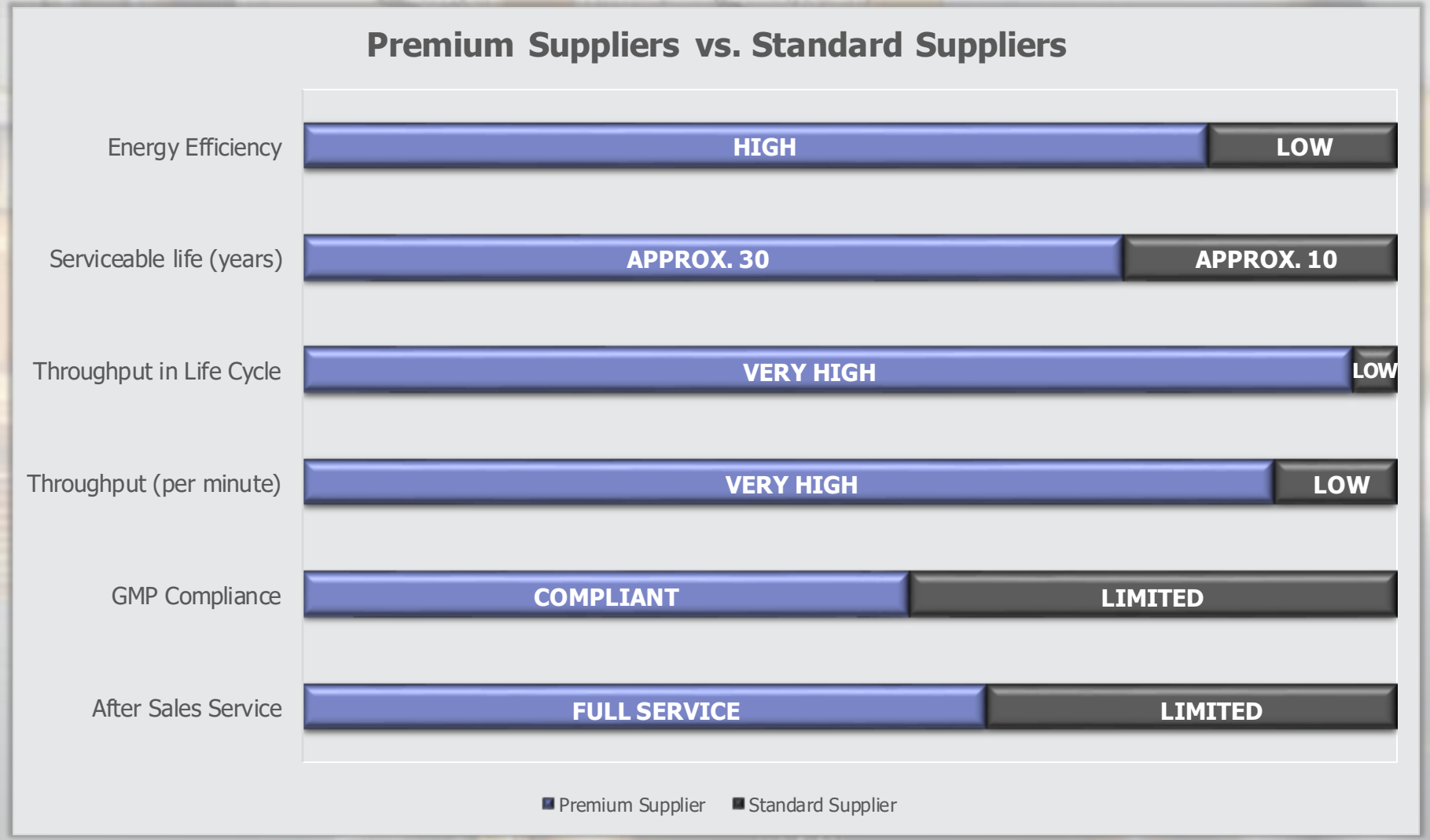
Examples

Process Equipment (Premium vs. Standard Suppliers)

Suppliers	Energy Efficiency	Throughput	Capital Cost	Maintenance Cost	Labour Cost	Durability	GMP Compliance	After Sales Service
Premium Supplier	High	2,000 pcs per minute	High	Low	Low	High	Yes	Yes (remotely possible)
Standard Supplier	Low	200-250 pcs per minute	Medium	High	High	Low	Possible but needs more support and documentation	Limited access to supplier technician (remotely not possible)

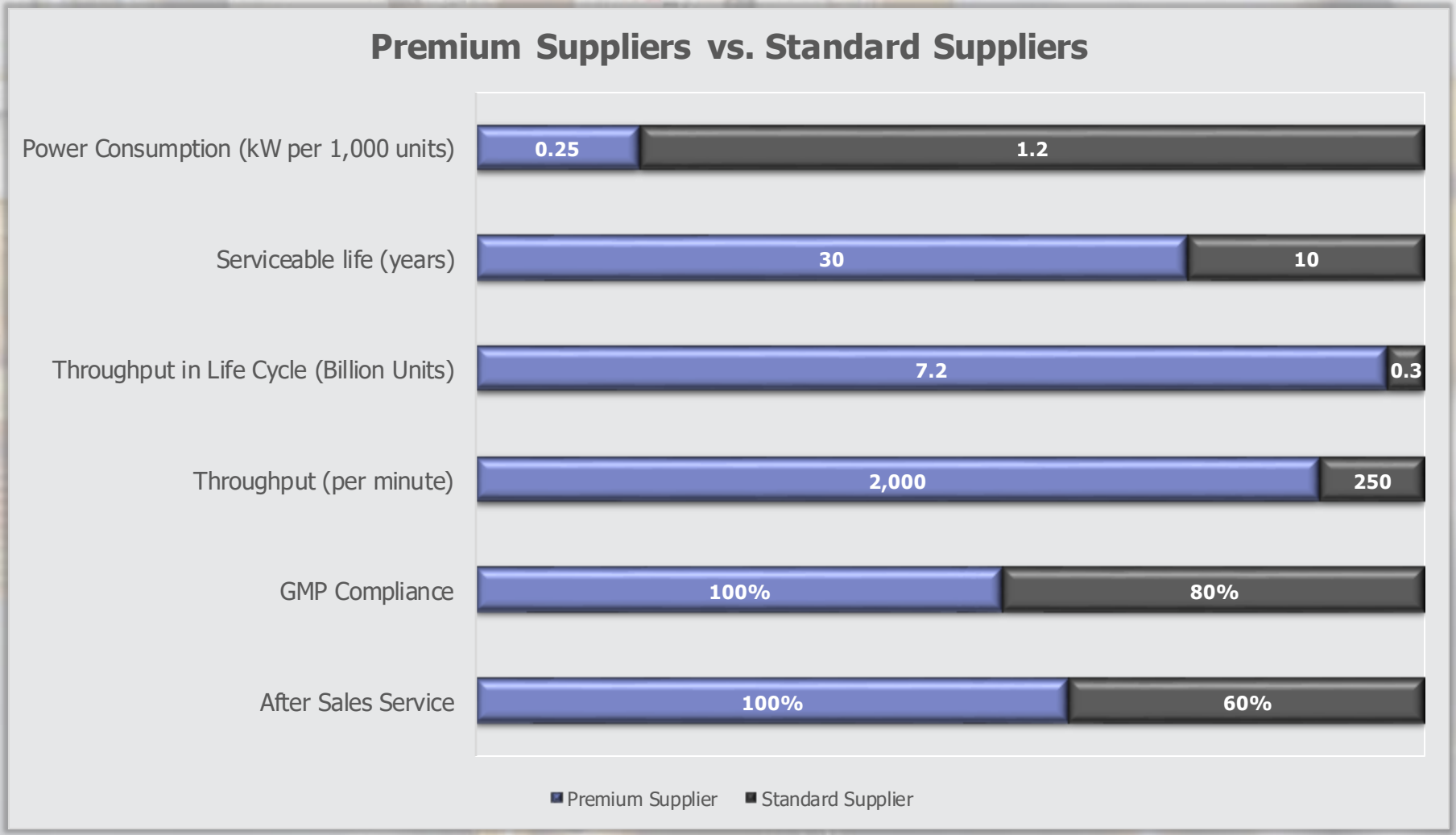
Environmental Impact Reduction

Process Equipment (Premium vs. Standard Suppliers)



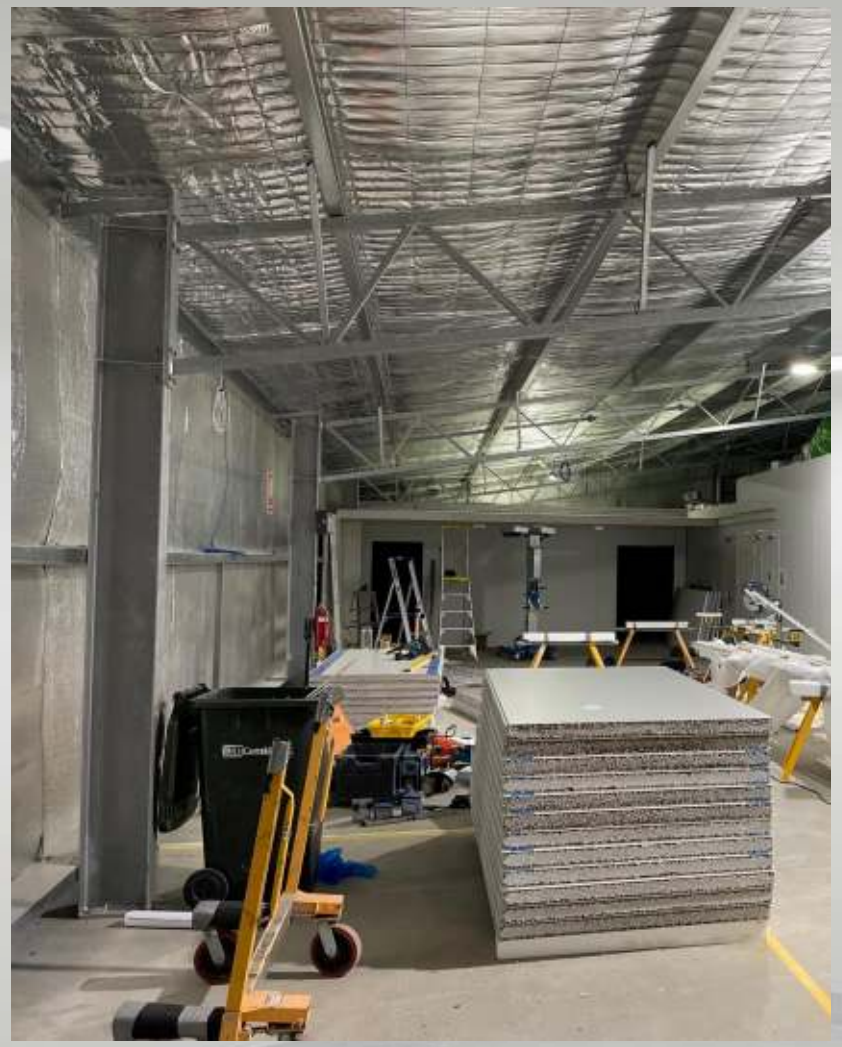
Environmental Impact Reduction

Process Equipment (Premium vs. Standard Suppliers)



Environmental Impact Reduction

Construction and built quality



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Environmental Impact Reduction
Operational Controls

- **Permanent reduction in airflow**
  - Original systems are usually over-designed (design margin)
  - At time of design you only have estimates of heat gains, particle loads, etc.
  - After 12-18 months you have much better understanding:
    - Now is the time to consider trimming = e.g. air volume reduction
    - Use available data to reduce whilst maintaining control at the required levels

Environmental Impact Reduction
Operational Controls

Reduction or set-back relaxation during silent hours:

- Temperature and RH
- Air velocity set-back (UDF and non-UDF) systems
- Turning systems off may also be ok for some less critical areas (e.g. secondary packaging)

Environmental Impact Reduction
Operational Controls

"Silent hour" temperature and RH relaxation:

- Normal practice in commercial properties
- Stay in control but relax set points or control bands during silent hours
- Restore control to defined levels in advance of processing start-up (qualify this time)
  - Allow temp rise in summer, drop in winter
  - Widen RH band

Environmental Impact Reduction
Operational Controls

Potential savings (UDF)

- Significant fan energy and some cooling energy can be saved by air velocity reduction:
  - Reduce UDF velocity from (average) 0.45 to 0.3 m/s
  - For example, fan volume would reduce from 10 m3/s to 6.7 m3/s, and the resistance in the system would reduce by ~75%
  - So this would give rise to a fan power saving of 10-15 kW during silent periods
  - Depending on the use of the facility, and the amount of "set-back" time available, this might be worth investing in

Environmental Impact Reduction

Operational Controls

Potential savings (Non-UDF)

- Some fan energy and some cooling energy can be saved by air volume reduction:
  - Reduce system volumes from 30→15 air changes/hr for a Grade B area, and 25→10 for a Grade C area as examples.
  - Such air volume reductions would give rise to reductions of around 50% in the fan energy consumed.
  - Again, depending on the use of the facility, and the amount of "set-back" time available, this might be worth investing in.
  - But there are some complications for cleanrooms (also applies to other pressurised spaces)

Environmental Impact Reduction
Operational Controls

Essential system components
for pressure control with volume set-back:

- Be aware: systems become more complex, hence greater cost, C&Q, maintenance, and failure potential (The RISK).
- Constant volume supply to each room needs to be reset.
  - Requires a VAV device.
- Room return air needs to be VAV to ensure fixed differential between supply and return air volume. This to maintain pressurisation leakage.

Environmental Impact Reduction

Operational Controls

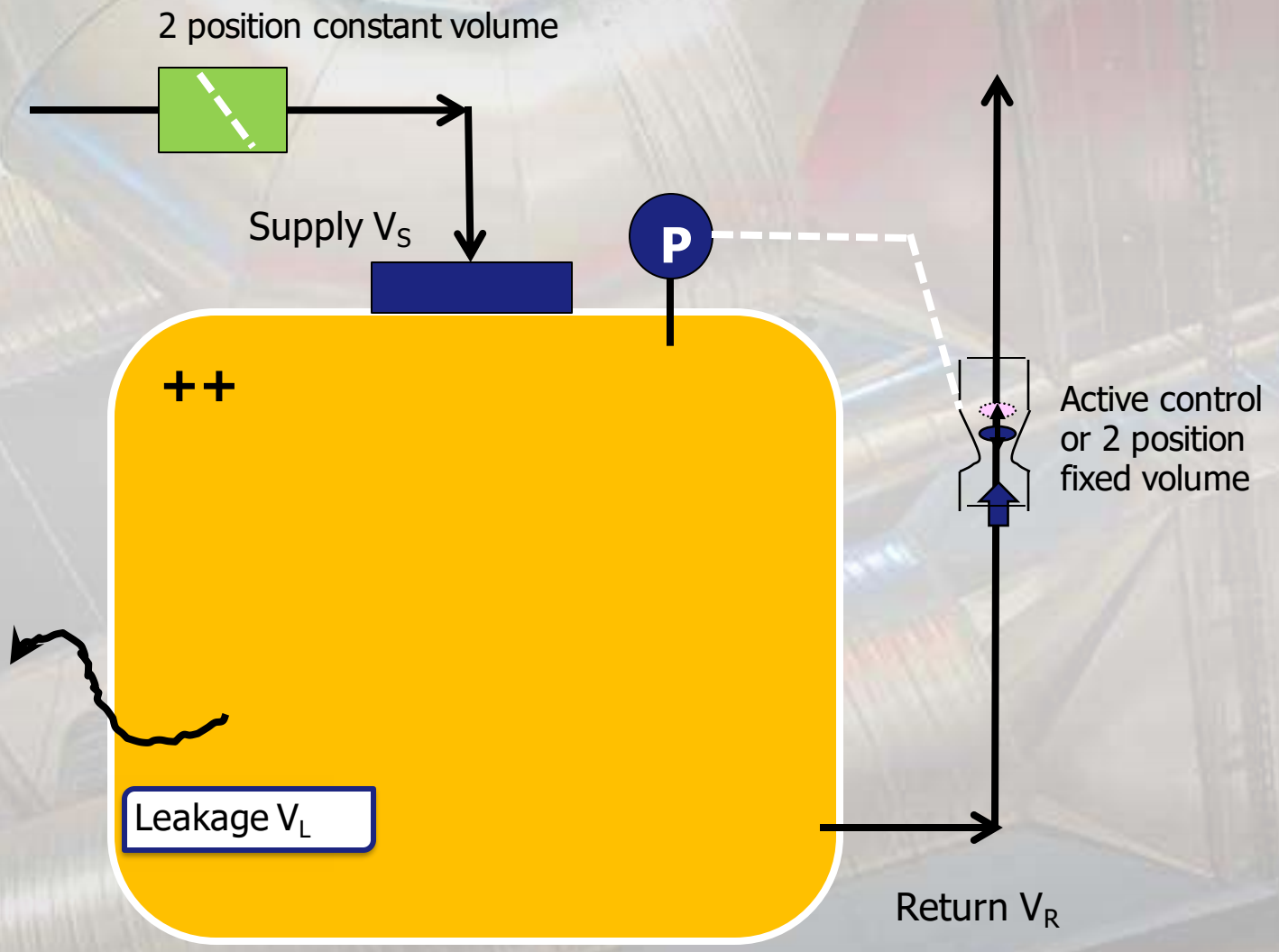
Leakage V_L is fixed for constant fixed room pressure

Supply V_s has 2 settings V_s & 0.3 V_s

Return V_R needs 2 settings, or to be active control

$V_{R1} = Vs - V_L$

$V_{R2} = 0.3\ V_S - V_L$



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Environmental Impact Reduction
Utilities

(Amazingly this is often forgotten).
Typical aspects to consider are:

- CHP (combined heat & power)
- Alternative de-humidification systems
  - Use of liquid desiccant systems (Lithium Bromide solution)
- New/upgraded chilled water systems
  - Electrically commutated motors (EC)
  - Refrigerant liquid pressure amplification (LPA)
  - Electronic expansion valves (refrigerant)
  - Optimal systems – 2 port; dual temperature systems

Is "building health" sustainable?

Sustainability is about consumption, climate protection, energy, but…

- **"Health and Wellbeing"** is one of 8 core umbrella categories under which the Passive House Standard contributes to the (international) Sustainable Development Goals:

  "Contributing to health and well-being by providing a cost-efficient, resilient and healthy environment for building users"

- IWBI administers the WELL Building Standard™ (WELL), being a:

  "performance-based system for measuring, certifying and monitoring features of the built environment that impact human health through air, water, nourishment, light, fitness, comfort and mind."

- GBCA partnered with IWBI to *promote:*

  "health and well-being in the design, construction and operations of buildings, fitouts and communities in Australia."

Thank you

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