OMICS Group
Accelerating Scientific Discovery

3rd International Summit on
GMP, GCP & Quality Control
September 25-26, 2014 Valencia, Spain

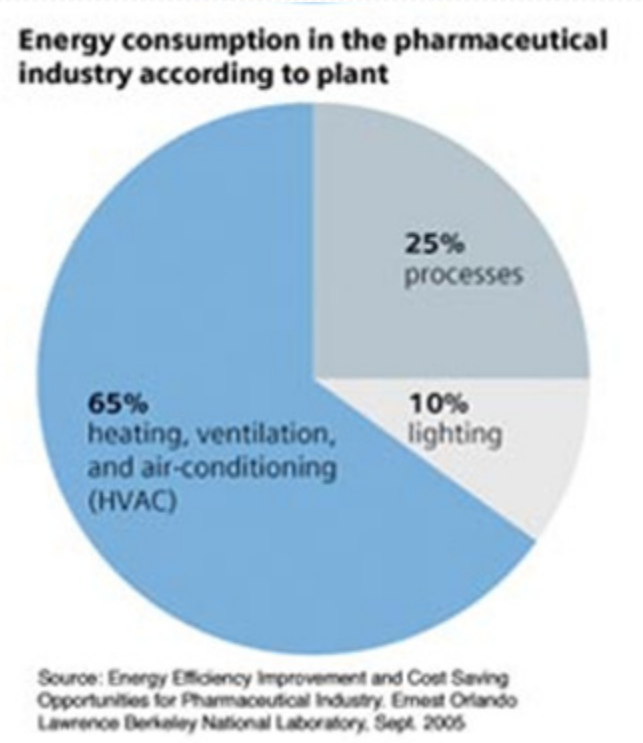
Lowering Facility Operational Cost by HVAC system Optimisation.

SysComm
Define • Deliver • Sustain

Sundar Chellamani
Technical Director
SysComm Project Management Ltd.

Operating Cost of HVAC system

HVAC system uses about 65% of overall plant energy usage



Focus of this presentation

- Reducing Energy costs
- Improving competitiveness
- More Environment friendly facility

There is huge scope in reducing HVAC operating costs without large investment

SysComm
Define • Deliver • Sustain

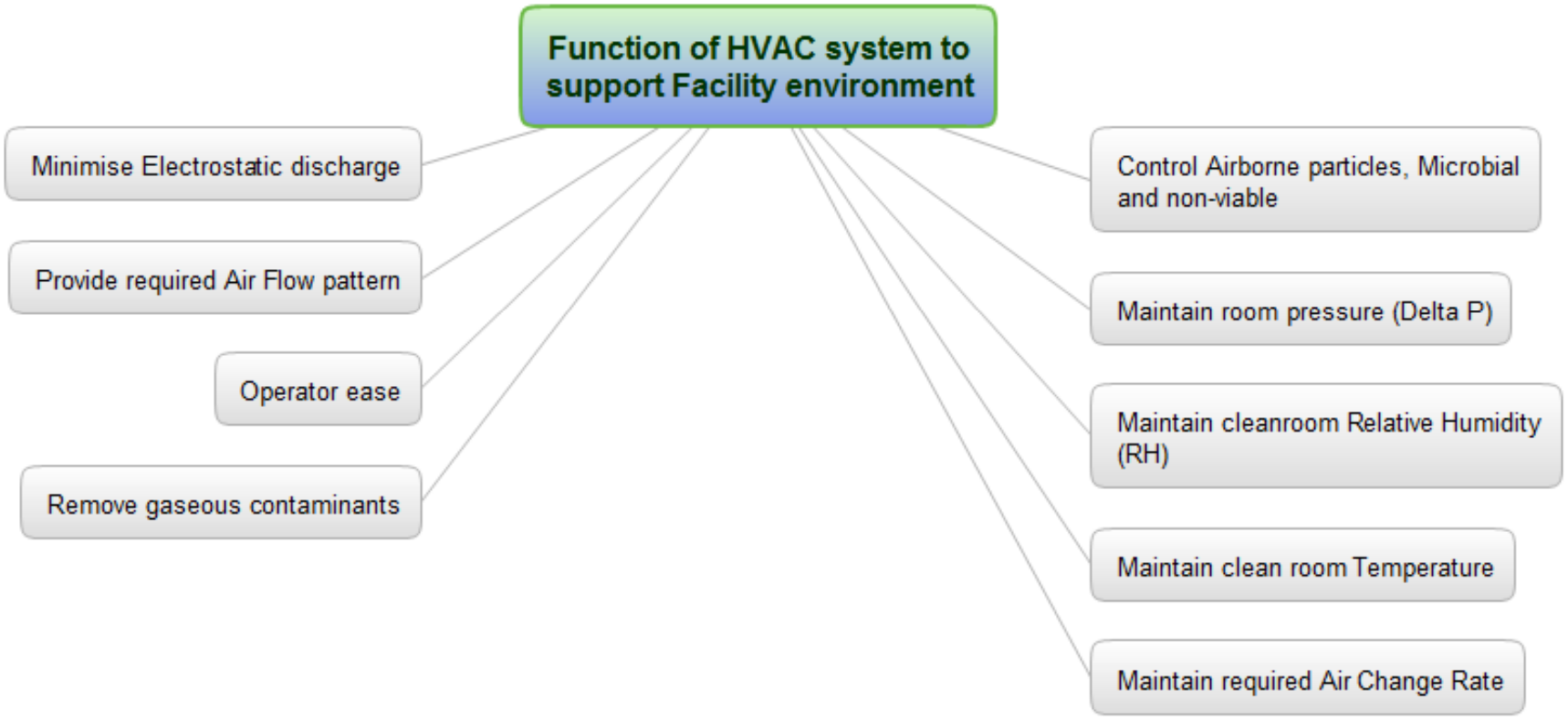
Definition of Cleanroom

ISO 14644-1 defines

A room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimise the *introduction, generation* and *retention of particles* inside the room and in which other relevant parameters, e.g.. Temperature, humidity and pressure are controlled as necessary.

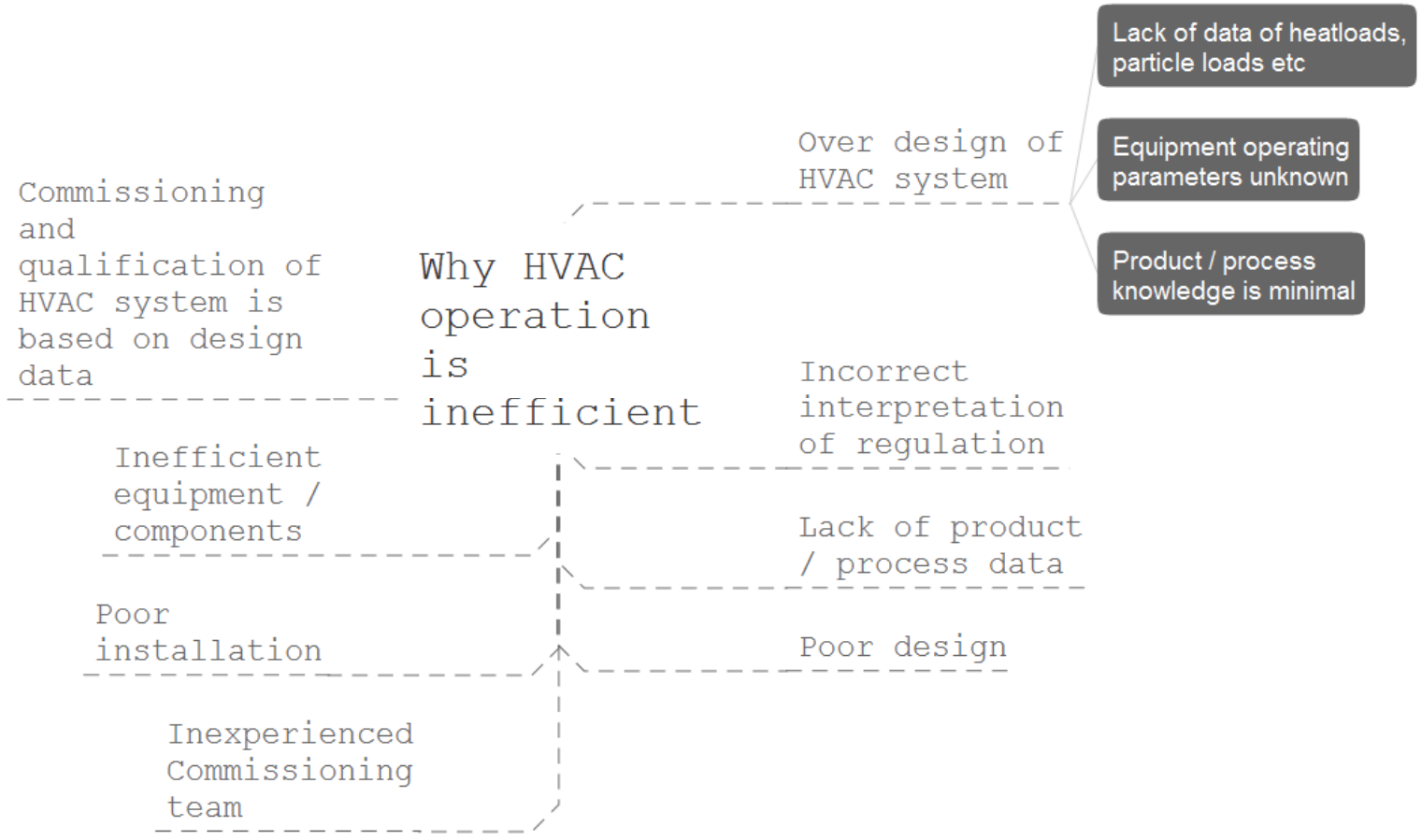
SysComm
Define • Deliver • Sustain

Function of HVAC system to support facility environment



SysComm
Define • Deliver • Sustain

Why HVAC Operation is inefficient



SysComm
Define • Deliver • Sustain

Common observation of Air change rates example

Company	Grade A	Grade B	Grade C	Grade D	CNC
Facility 1	0.5 m/s	30 acph	20 acph	15 acph	15 - 20 acph
Facility 2	0.45 m/s	45 acph	25 acph	15 acph	15 acph
Facility 3	0.45 m/s	60 acph	40 acph	25 acph	15-20 acph

Acceptance criteria for cleanroom validation is different for different companies.

Most of the cleanrooms across the globe are over designed with respect to product / process requirements and regulatory expectation.

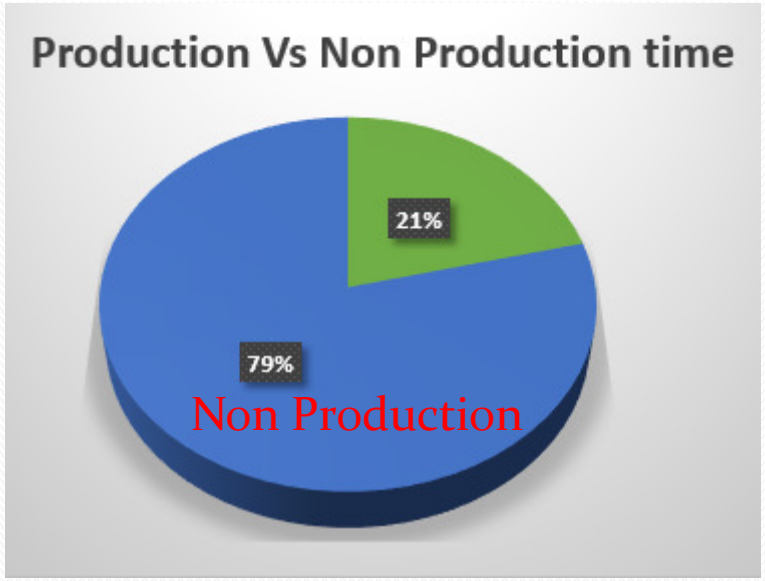
SysComm
Define • Deliver • Sustain

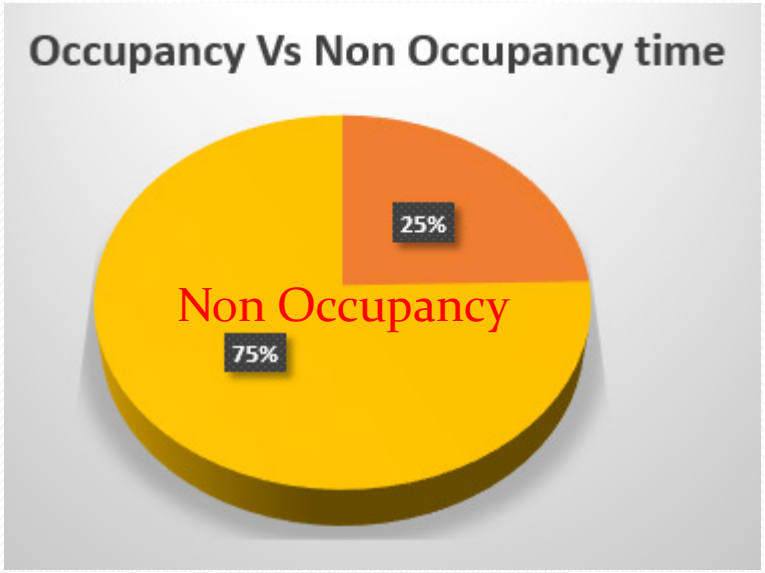
Common Observation on HVAC Operation with respect to higher energy utilisation

1. Higher air change rates.
2. Higher cleanroom classification
3. Higher pressure difference between rooms / zones
4. Too much fresh air usage
5. Tighter tolerance for temperature and humidity
6. Higher unidirectional flow velocity
7. Constant steady operation of the facility regardless of production schedules or office occupancy

SysComm
Define • Deliver • Sustain

Typical Facility Usage and Occupancy





Assuming one shift operating facility

SysComm
Define • Deliver • Sustain

How efficient is your HVAC system?

What is the Plant energy cost per year?

Is there a scope for reduction in HVAC operating cost?

What is the HVAC operating cost per year?

Can an assessment be made on the energy usage?

SysComm

Define • Deliver • Sustain

Challenges / Barriers of high HVAC system operating costs?

The following are some common challenges/barriers for why facilities avoid the optimisation of cleanrooms:

- Lack of site resources within the organisation
- QA / Validation – don't want to make changes
- Complex change control system
- Difficulty finding the right expertise / consultant
- Energy reduction is not a priority in the organisation
- No available downtime for the cleanroom
- Any change after qualification is perceived as regulatory risk.
- Risk of getting back on track after any shutdown to keep up the production schedule

SysComm
Define • Deliver • Sustain

Create a Road map for Optimisation

The Six Sigma DMAIC (Define, Measure, Analyse, Improve, Control) methodology can be thought of as a roadmap for problem solving and HVAC improvement.

STEPS

Stage	Tasks
Define	Calculate EUI, benchmark against industrial average.
Measure	Collect and organise energy consumption data, breakdown consumption into various areas and identify the major consumers of energy.
Analyse	Study the energy consumption pattern and find the root cause of high waste.
Improve	Develop and implement strategies to minimise waste and reduce energy consumption.
Control	Monitor the process after change and observe the level of improvement and sustain.

SysComm
Define • Deliver • Sustain

Define and set achievable HVAC Energy goals

DEFINE

- Calculate Energy Utilisation Index (EUI) of the facility

  Definition of EUI: Measure of total energy consumed in heating or cooling a building or facility over a period of time. Common unit is kWh/ m²/year.

  Industry Average ~ 215 kWh/ m²/year

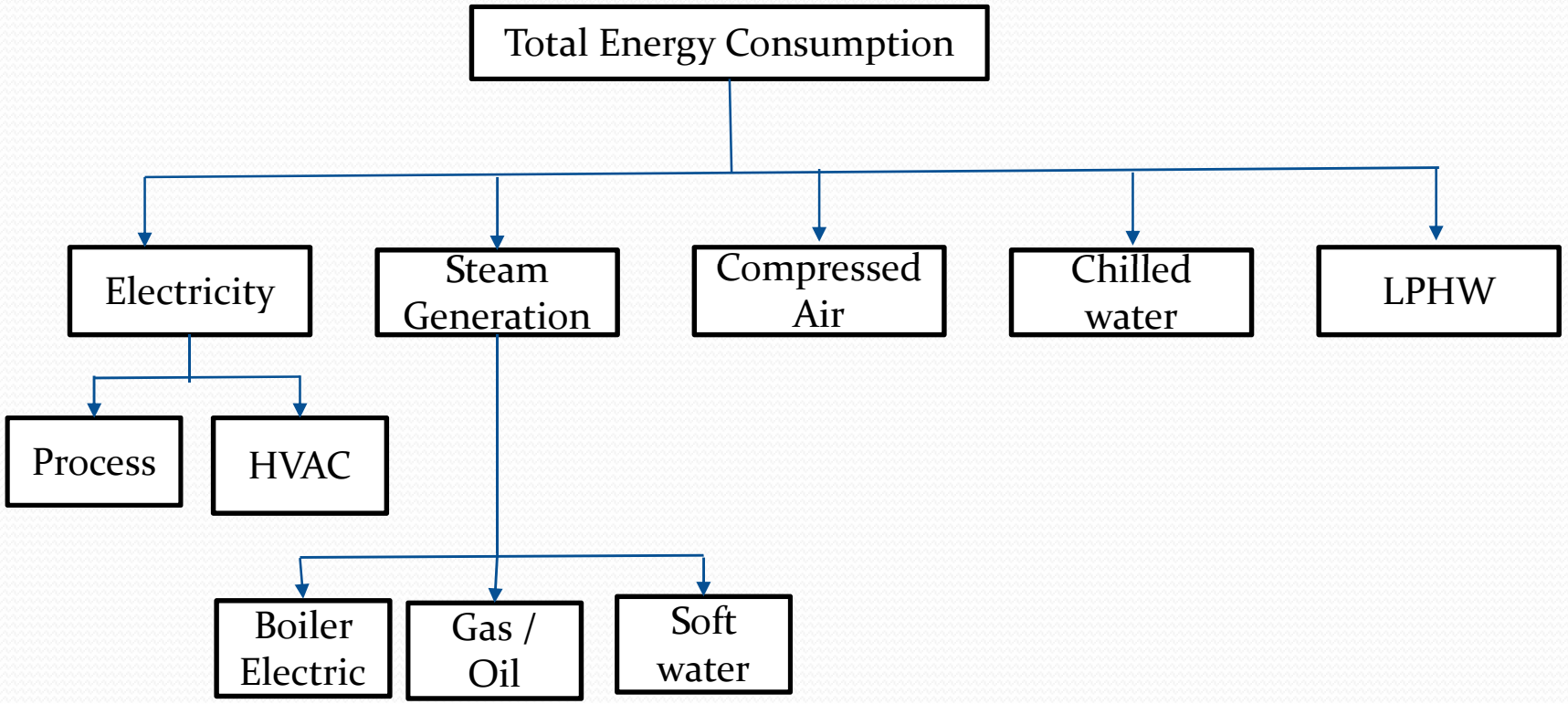
- Benchmark the facility energy consumption against the industry average
- After benchmarking, set achievable energy reduction goals and define 'what is success'
  - E.g. Percent energy reduction

SysComm
Define • Deliver • Sustain

Create Energy Utilisation Index

Collect and organise energy consumption data, breakdown consumption into various areas as indicated on the chart below

MEASURE



SysComm
Define • Deliver • Sustain

Collect all relevant data over a period

Make sure the required metering devices are available and calibrated for use.

MEASURE

Month	Electricity		Natural Gas		Steam	
	Facility reference		Facility reference		Facility reference	
	Meter		Meter		Meter	
	Energy	Total Cost	Energy	Total Cost	Energy	Total Cost
	kWh	€	Cu.m	€	Kgs	€
Jan						
Feb						
Mar						
Apr						
May						
Jun						
Jul						
Aug						
Sep						
Oct						
Nov						
Dec						

SysComm
Define • Deliver • Sustain

Optimisation example – Scope of reduction

ANALYSE

Optimisation example: Based on theory

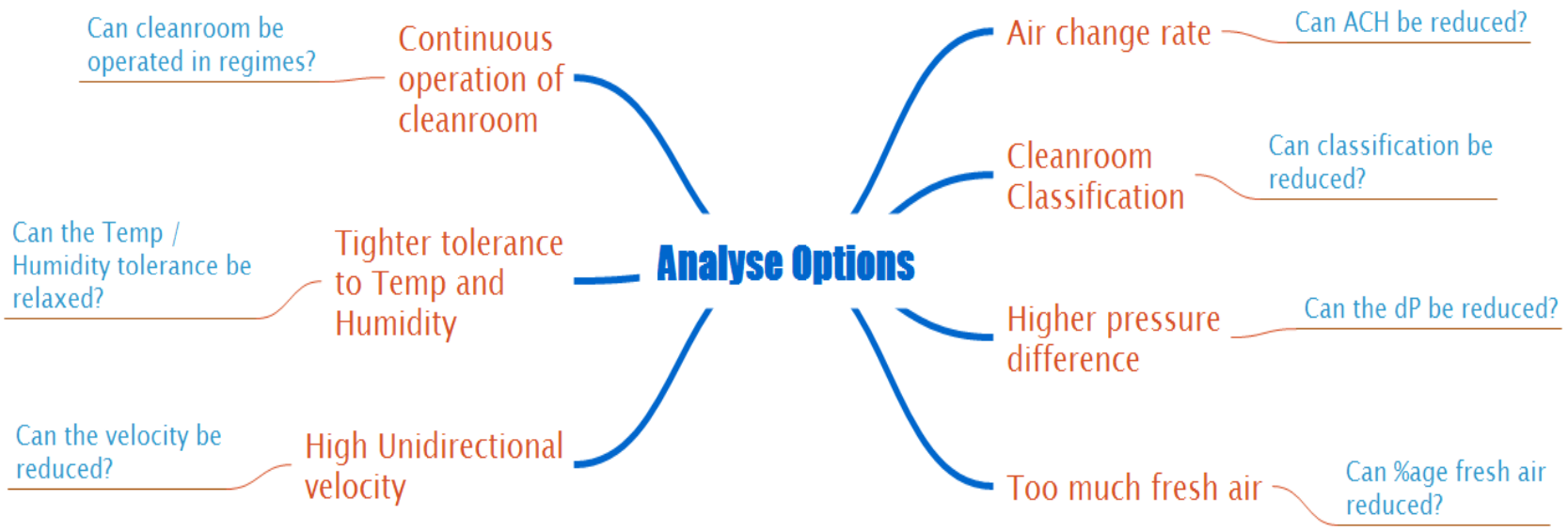
Flow rate is proportional to the rotational speed of the fan motor, i.e. if flow is halved, power is reduced by factor of 8 and pressure is reduced by factor of 4.

A small change in the rotational speed leads to significant change in power consumption. Nothing is too little.

SysComm
Define • Deliver • Sustain

Analyse options based on collected data

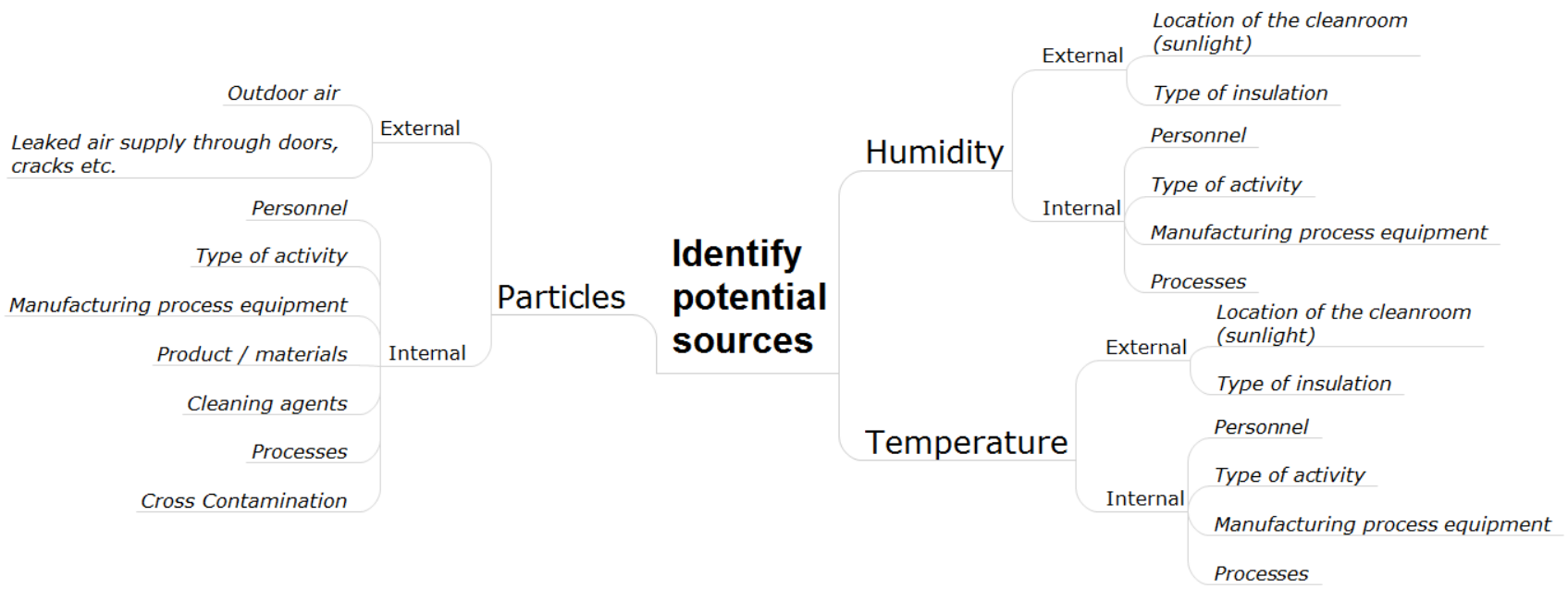
ANALYSE



SysComm
Define • Deliver • Sustain

Identify potential sources that induce parameters variation

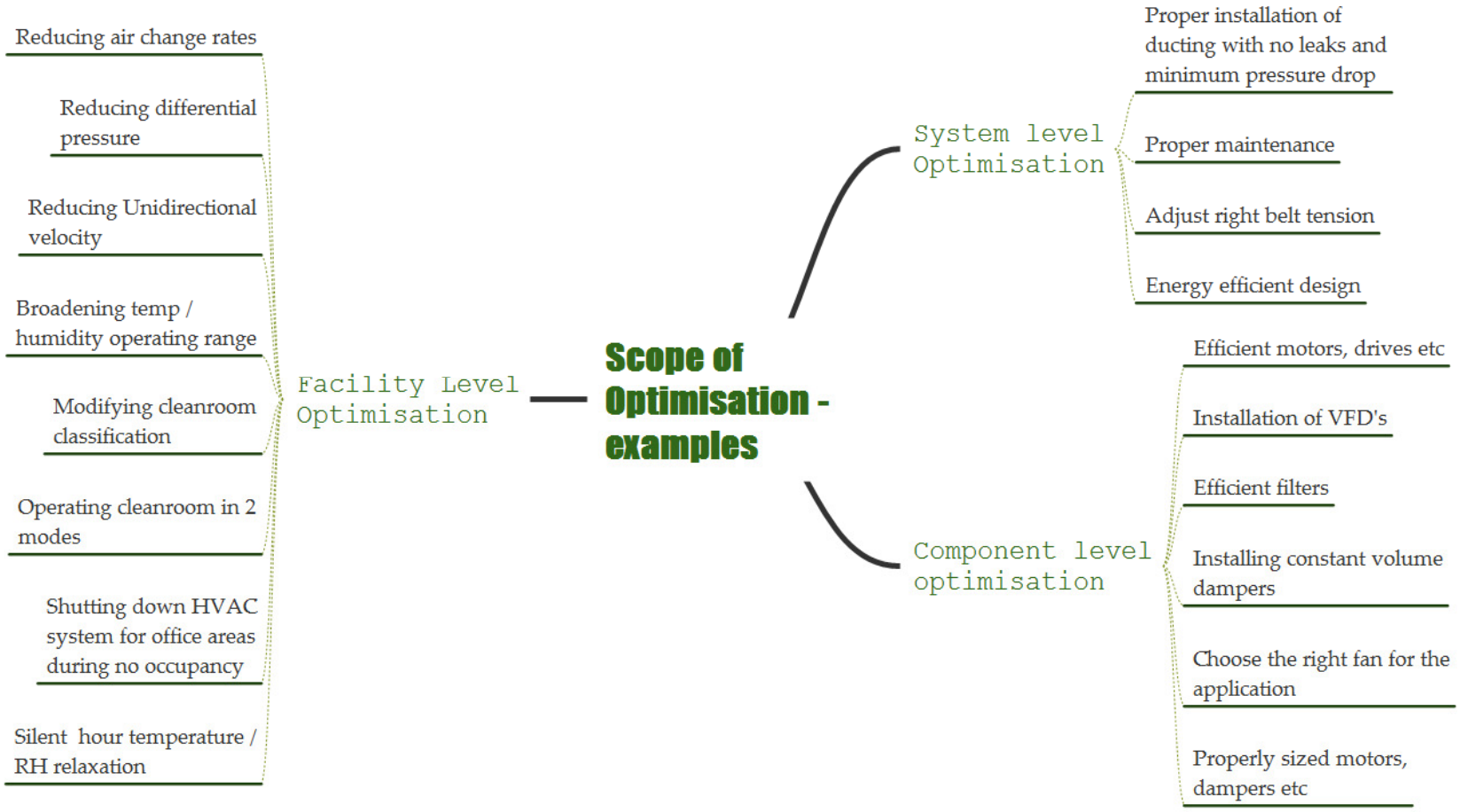
ANALYSE



SysComm
Define • Deliver • Sustain

Scope of Optimisation - Examples

ANALYSE



SysComm
Define • Deliver • Sustain

Not all changes require QA approval

High level sequence

ANALYSE

Any Energy reduction effort of a qualified cleanroom must be assessed and approved by relevant QA team prior to implementation.

The following steps are proposed:

1. Conduct energy studies to justify potential reduction in operating cost before implementation.
2. Conduct Quality Risk Assessments (QRA)
   - To be conducted by a multidisciplinary team inclusive of QA / QC discipline.
3. Collect additional data based on observation from QRA through additional QC experiments.

SysComm
Define • Deliver • Sustain

Identification of risks through QRA

ANALYSE

Quality Risk Assessment – *as per ICH Q9*

Conduct QRA as a multidisciplinary team inclusive of QA, QC, Validation, Engineering and Operations.

- Set a target reduction of operating parameters within compliance band
- Identify all potential quality risks through conducting proper risk assessment as per ICHQ9.
- QC to collect supporting data over a period to justify the proposed reduction (must have no quality impact)
- Complete a risk assessment table based on observed results

SysComm
Define • Deliver • Sustain

Identification of risks through QRA

Example as below

ANALYSE

HVAC RISK ASSESSMENT - EXAMPLE														
				Initial						Revised				
HVAC Current configuration	**HVAC proposed configuration**	**Potential Failure**	**Potential effect of failure**	**Severity**	**Probability**	**Detectability**	**RPN**	**Proposed experimental studies**	**Proposed experimental studies**	**Severity**	**Probability**	**Detectability**	**RPN**	**Proposed modifications**
Air change rate at 25 acph	Reduction in air change rate up to 15 acph	Increased particles in the room	Product contamination	9	9	6	81	Reduce the air change rate in steps and monitor the collect room particulate data for both viables and non-viables	Reduce the air change rate in steps and monitor the collect room particulate data for both viables and non-viables	**9**	**3**	**6**	**27**	The air change rate can be reduced to 18 acph based on the experimental data.
		Recovery times do not meet requirement	Product contamination	9	9	6	81			**9**	**3**	**6**	**27**	

SysComm
Define • Deliver • Sustain

Implement Energy Optimisation – as example

IMPROVE

Implement energy optimisation based on outcome of QRA

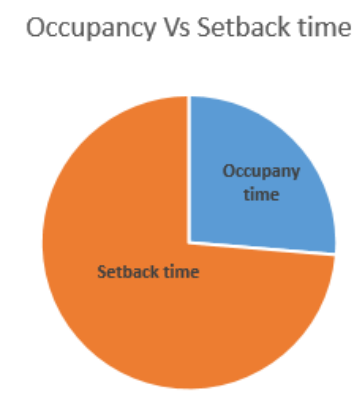
1. Air change rate reduction reducing air volumes
2. Reduction of UDF velocity (0.45m/s) from average to appropriate velocity.
3. Operating at 2 air change rate flow regimes
4. Silent hour temperature and RH relaxation
5. Shutting down HVAC systems on unused non-production areas.
6. Re-evaluation on HEPA filter replacement frequency
7. Setting the right RH based on product / process requirements

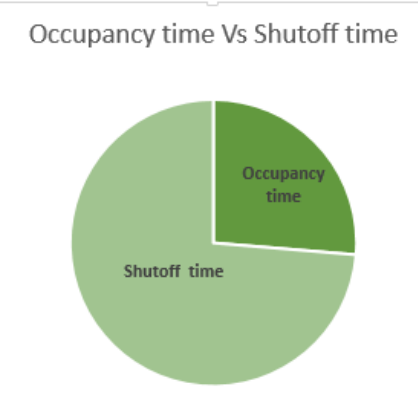
SysComm
Define • Deliver • Sustain

Monitor, Observe and Sustain

CONTROL

- Implement all changes for sustained operation
- Monitor the process after change and observe the level of improvement using statistical methods.
- Confirm that the cleanroom operations are within the product / process requirements and operates as per regulatory compliance.





SysComm
Define • Deliver • Sustain

Conclusion

- HVAC system operations optimisation can provide significant savings in plant operational costs
- The following combined skills are essential to perform a HVAC systems optimisation
  - Knowledge in Commissioning, Qualification and Operation of HVAC systems
  - Possess understanding of Energy Management
  - Possess understanding of regulatory aspects of cleanroom

SysComm
Define • Deliver • Sustain

Thank You

Sundar Chellamani

Technical Director

SysComm Project Management Limited

3015 Lake Drive

Citywest Business Park

Dublin 24

Ireland

sundar.chellamani@syscomm.ie