WB Engineers+ Consultants

bioX

OPTIMIZING MANUFACTURING

Designing and Implementing Open and Closed Process Systems

hello.

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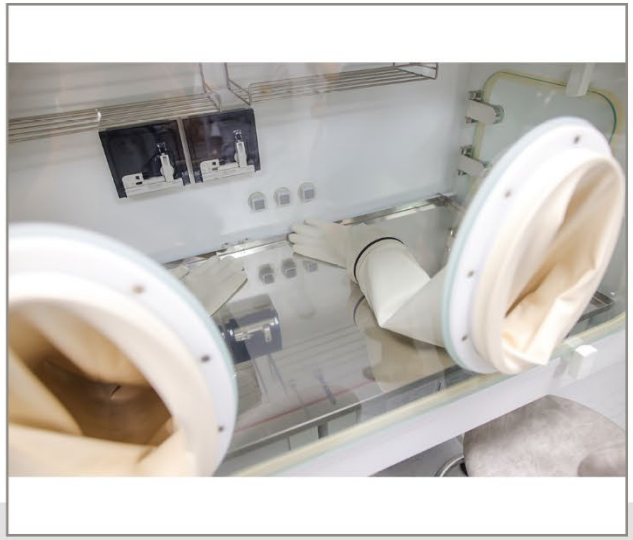
quick poll

not every
GMP manufacturing facility is the same

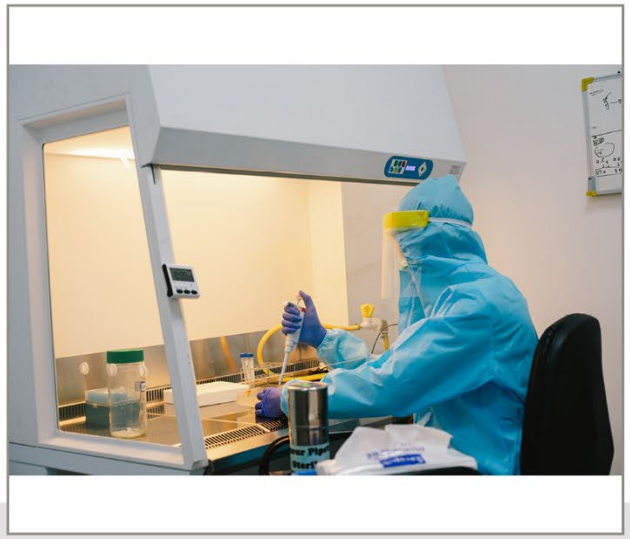
key differences

	Cell Therapy	Gene Therapy
Target	cell themselves	gene inside cells
Mechanism	infusion of healthy or engineered cells	modification or replacement of DNA/RNA

manufacturing suite **equipment**



ISOLATOR
closed system



BIOSAFETY CABINET
closed system

INCUBATORS
open/closed system

CELL PROCESSOR
closed system

choosing the **right environment**

process closure **risk assessment**

DISCOVERY

PROCESS RISK IDENTIFICATION

UMREMEDIATED RISK ASSESSMENT

FINAL UMREMEDIATED RISK ASSESSMENT

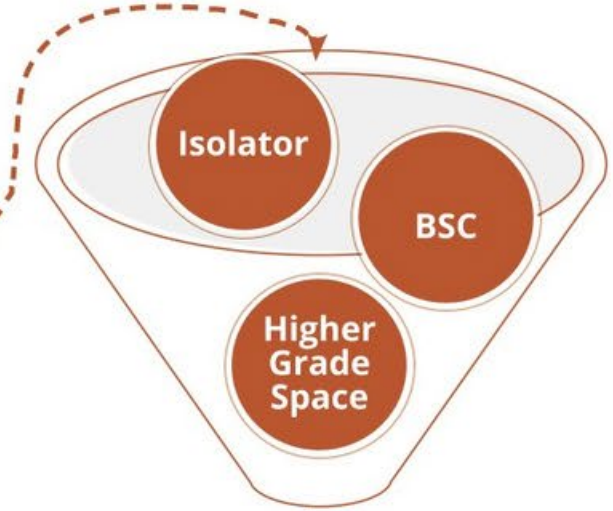
Process Docs (MBRs, SOPs, etc.)

All Processing Manipulations Identified

Phase 1 Process Closure Risk Assessment

Phase 2 Process Closure Risk Assessment

Identified Open Processing Step Risks



Assess options for addressing each processing step risk

Process Risk
Regulator Risk
Capital Cost
Operational Cost

open vs. closed systems

impact on infrastructure

1 product quality

impact on infrastructure

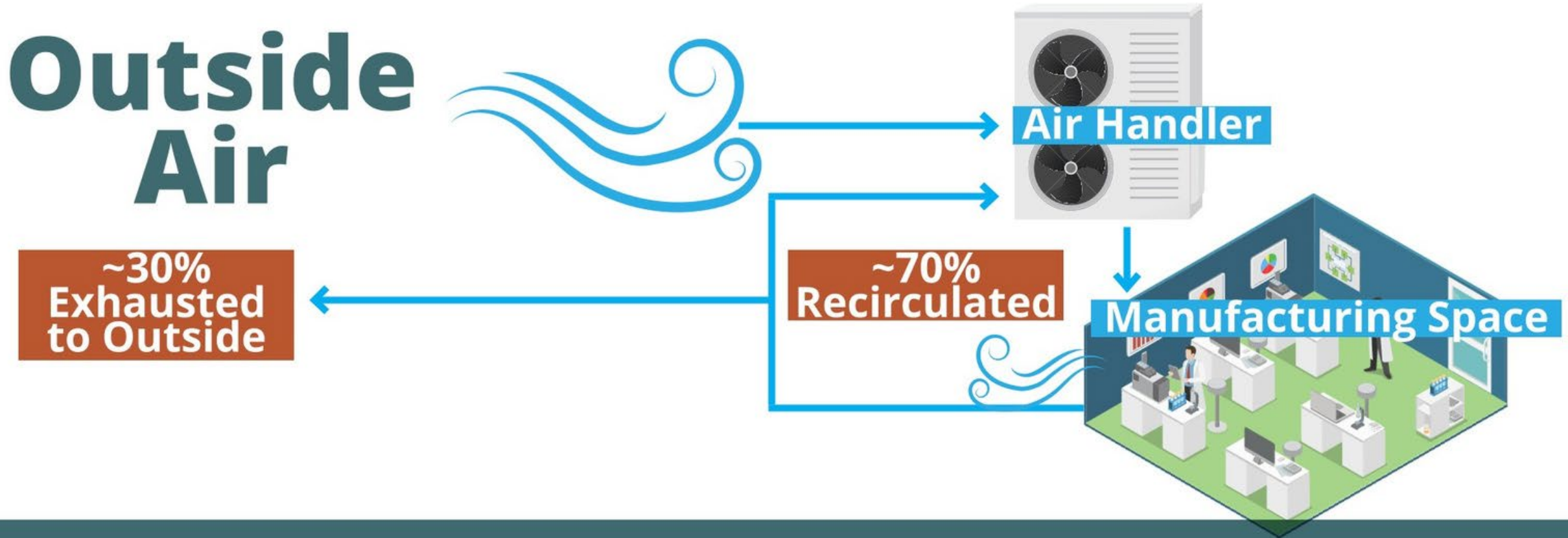
impact on infrastructure

impact on
infrastructure

technical and **business impact**

recirculated air
risk assessment for segregation

better efficiency



once through air
best for segregation

worst for efficiency

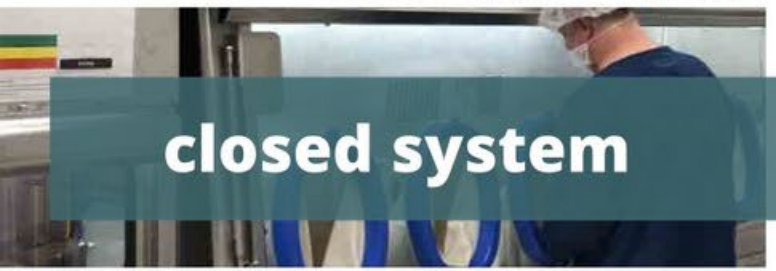
Outside Air

Air Handler

Manufacturing Space

100% Exhausted to Outside

cost

	manufacturing equipment	building construction	operations/ energy
	↓	↓	↓
 open system	$	$$	$$
 closed system	$$	$	$


real world
scenarios


Align **compliance**, **risk**,
and **cost** to choose the
system that supports
your long-term goals

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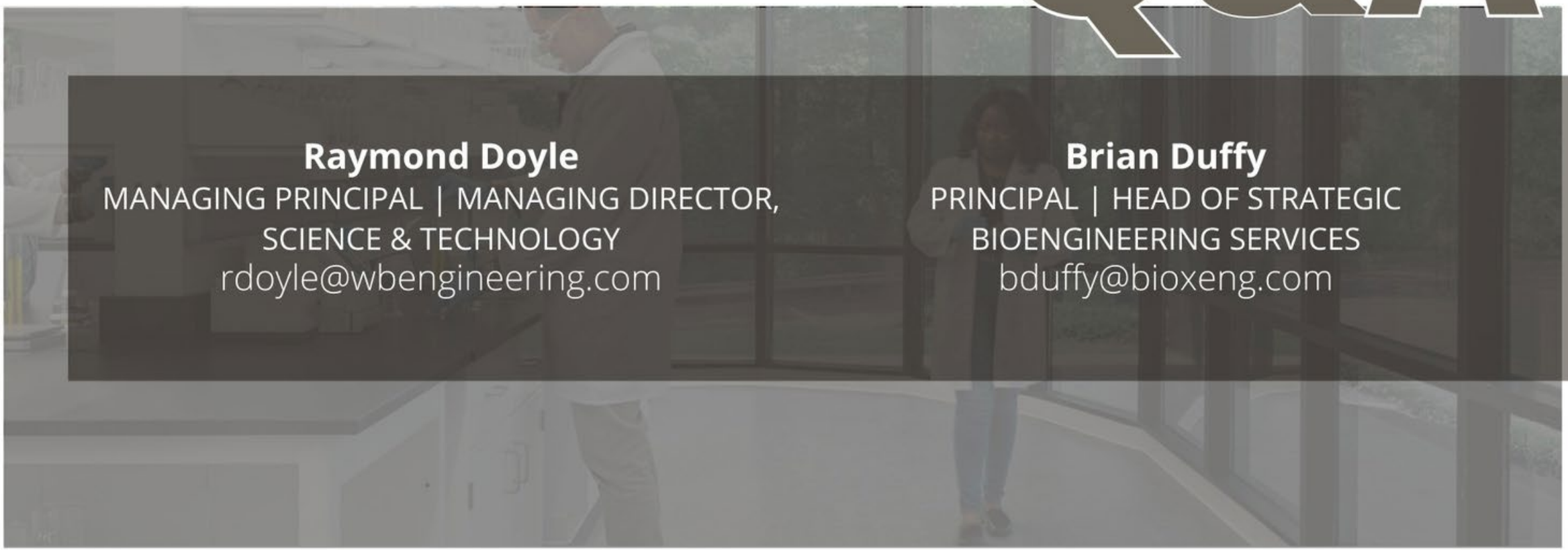
Q&A



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