

# Rapid Micro Biosystems

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MARCH 2022



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# Leadership

Strong leadership with deep domain expertise

## COMPANY LEADERSHIP TEAM



**Rob Spignesi**  
President & CEO



**Sean Wirtjes**  
CFO



**Andy Keys**  
CCO



**John Wilson**  
COO



**Vicki Vezina**  
CHRO



**Jonathan Paris**  
SVP & General Counsel



**Gurinder Grewal**  
SVP of Strategy



**Kristine Williams**  
VP of R&D

## BOARD MEMBERS



**Jeffrey Schwartz**  
Bain Capital Life Sciences



**David Hirsch**  
Longitude Capital



**Melinda Litherland**  
Independent Director



**Rob Spignesi**  
President & CEO



**Richard Kollender**  
Quaker Partners



**Alexander Schmitz**  
Endeavour Vision



**Nat Ricciardi**  
Independent Director



**Inese Lowenstein**  
Independent Director

## COLLECTIVE EXPERIENCE




## Our vision

We are revolutionizing a critical, regulated part of the global pharmaceutical manufacturing process, bringing microbial quality control into the 21<sup>st</sup> century

**Creating the future of microbial quality control**


# Microbial quality control (MQC) market is poised for disruption


 **\$1 trillion** Global prescription drug market

 **55%** Biologics share of top 100 prescription drug sales by 2026

 **1,000+ trials**  
**13 approved** Cell and gene therapy pipeline

 **350 million** MQC tests annually in pharma to ensure the safety of drugs

 **95%+** Share of current MQC tests performed with a manual, slow process subject to human error

 **Increasing regulatory scrutiny** Mandated by FDA / global regulators; 4x increase in number of FDA warning letters per year with data integrity findings after 2015

## ANNUAL GLOBAL MQC TEST VOLUME BY GEOGRAPHY





# Growth Direct™ platform fully automates and modernizes MQC

The only fully automated,  
high-throughput and secure MQC solution...



Proprietary  
Consumables



Data &  
Software



Global  
Validation  
& Support  
Services

THE GROWTH DIRECT PLATFORM

...delivering a compelling value proposition...

Data  
Integrity



Operational  
Efficiency



Insight &  
Accuracy



- Supports global quality **regulatory compliance** and improved data handling and management
- Enables **faster decision making** by accelerating time to results by 50% or faster compared to the traditional method
- **Eliminate human quality control errors**, preventing costly recalls and regulatory interventions

...driving rapid global adoption

100+

cumulative  
instruments placed

1M+

cumulative  
consumables sold

>50%

of top 20 pharma  
companies as  
customers\*

~60%

customers with  
multiple systems

**~70**  
MANUFACTURING  
SITES

**Our top-tier customer base  
includes the majority of top  
20 global pharma\***

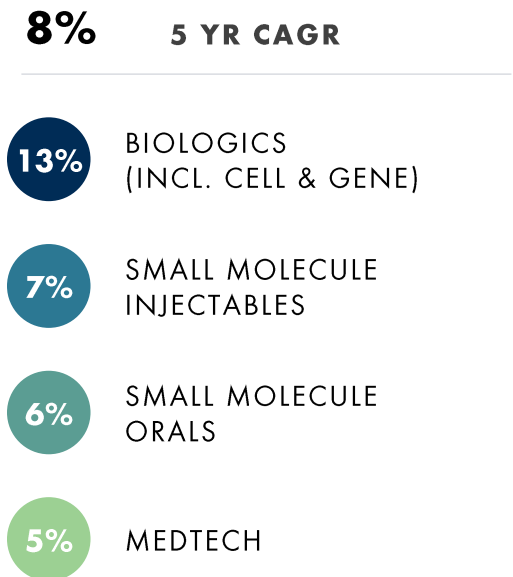
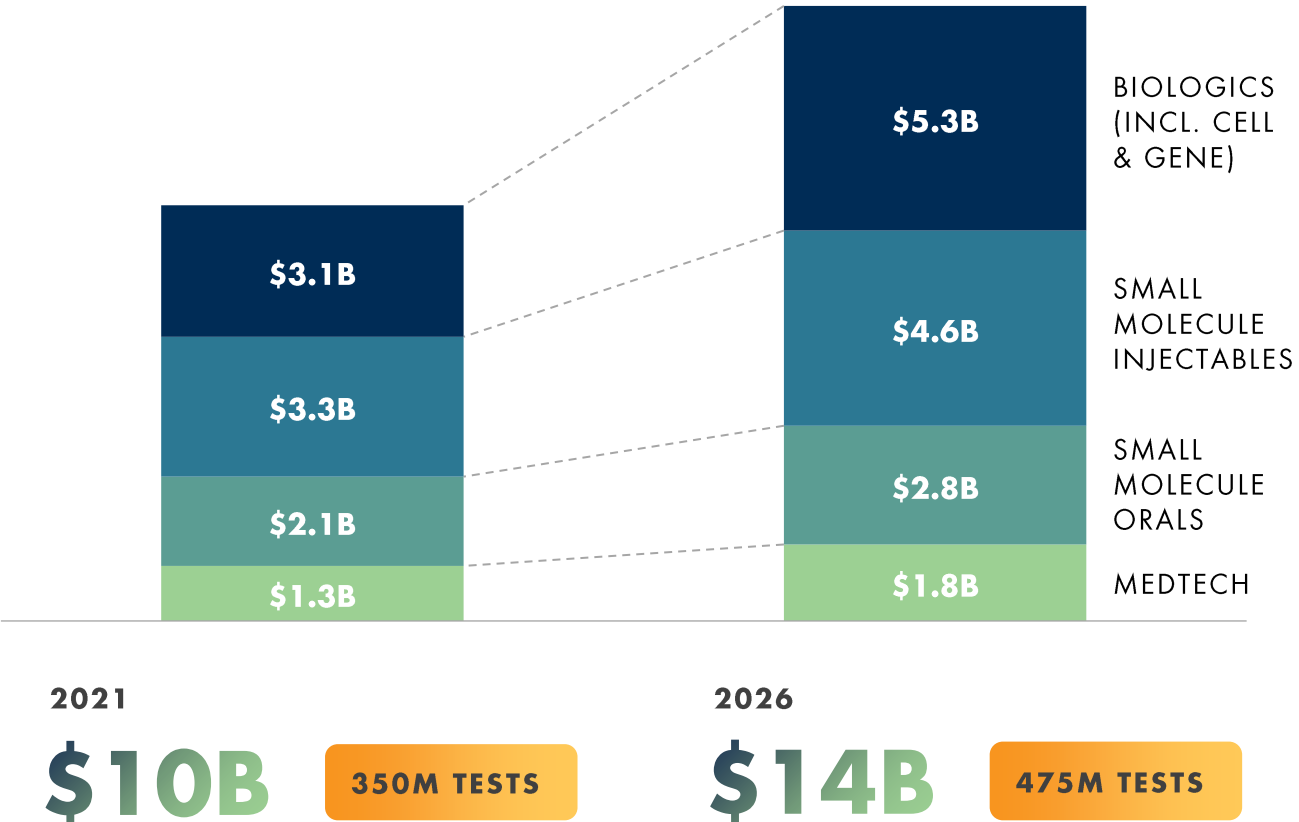
CUSTOMER SEGMENTS WITH ESTABLISHED USE

- Biologics
- Cell & Gene Therapy/ CAR-T
- CDMO
- Small Molecules
- 503B Compounders
- Personal Care Products

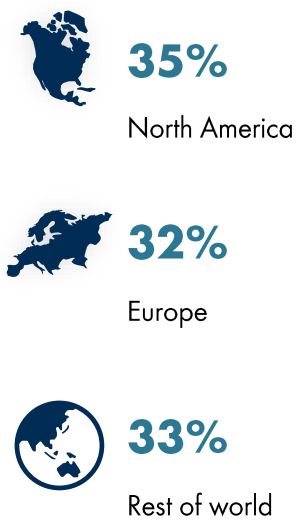
GEOGRAPHIES WITH SOLD INSTRUMENTS



# The addressable market for MQC testing is large and growing

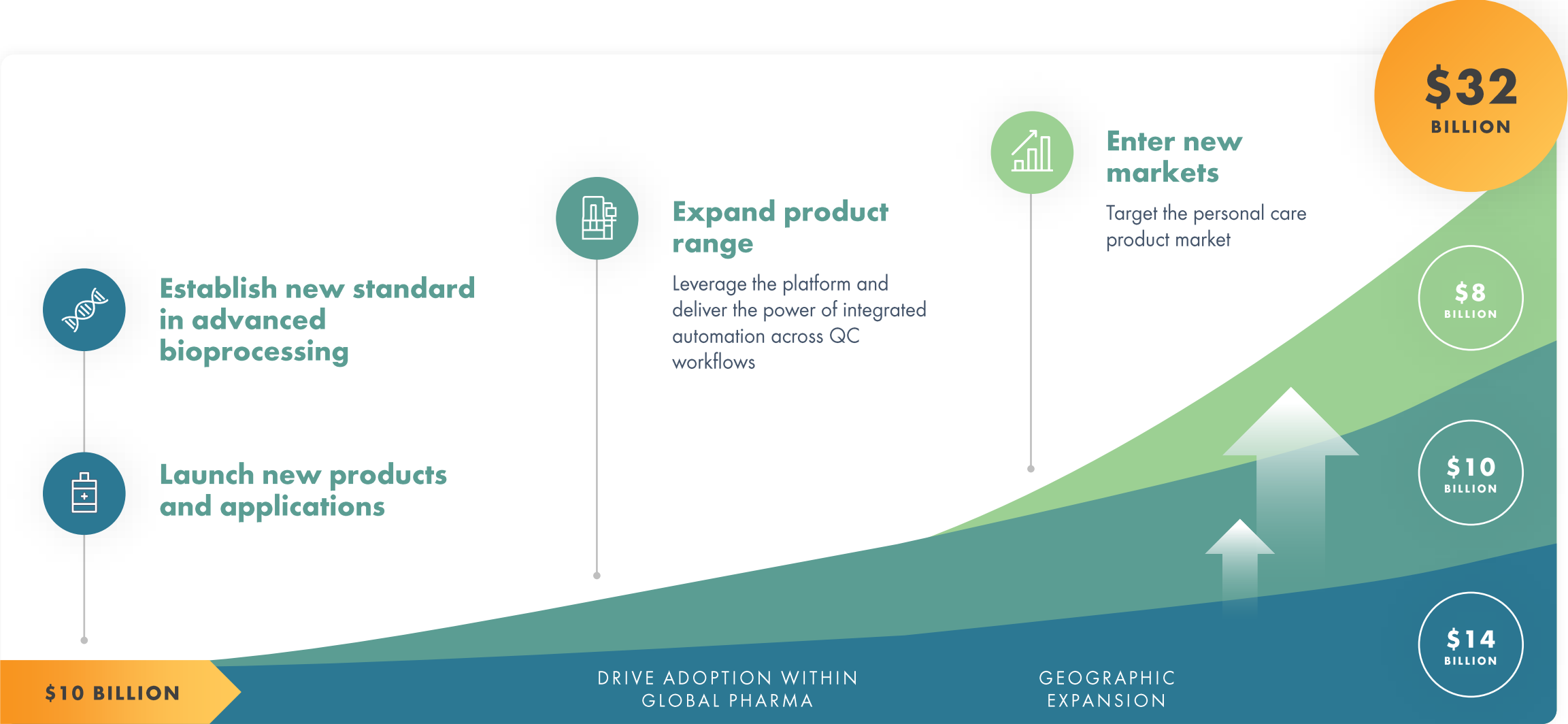


## GLOBAL INDUSTRY TEST VOLUME BY GEOGRAPHY





# Investing to unlock major TAM expansion opportunities



# Our growth strategy

Our growth strategy unlocks a total TAM = **\$32 billion**

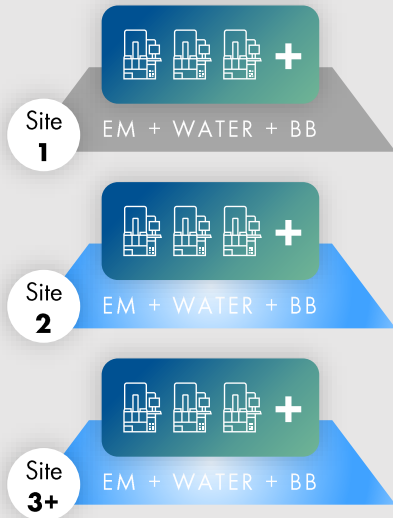
## GROW NEW CUSTOMER ADOPTION

Target manufacturers across pharmaceuticals and CDMOs



## DRIVE ENTERPRISE DEPLOYMENTS

Place more systems across our customers' global site networks and drive higher utilization



## EXPAND INTO NEW GEOGRAPHIES

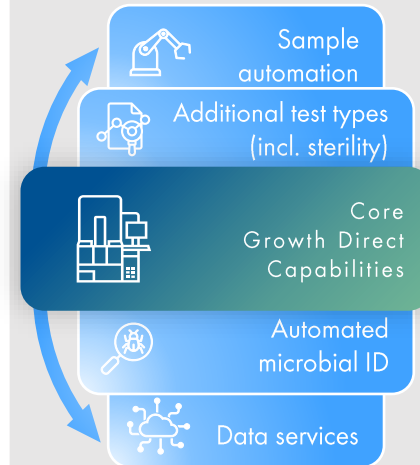
Build up commercial and operational footprint in Asia-Pacific and Eastern Europe



## LAUNCH NEW PRODUCTS AND SERVICES

New systems, consumables, software, and data services to deliver integrated QC automation

Selective M&A to expand portfolio



## PURSUE ADJACENT MARKETS

Target adjacent markets such as personal care products



**\$10**  
BILLION

**\$14**  
BILLION

+

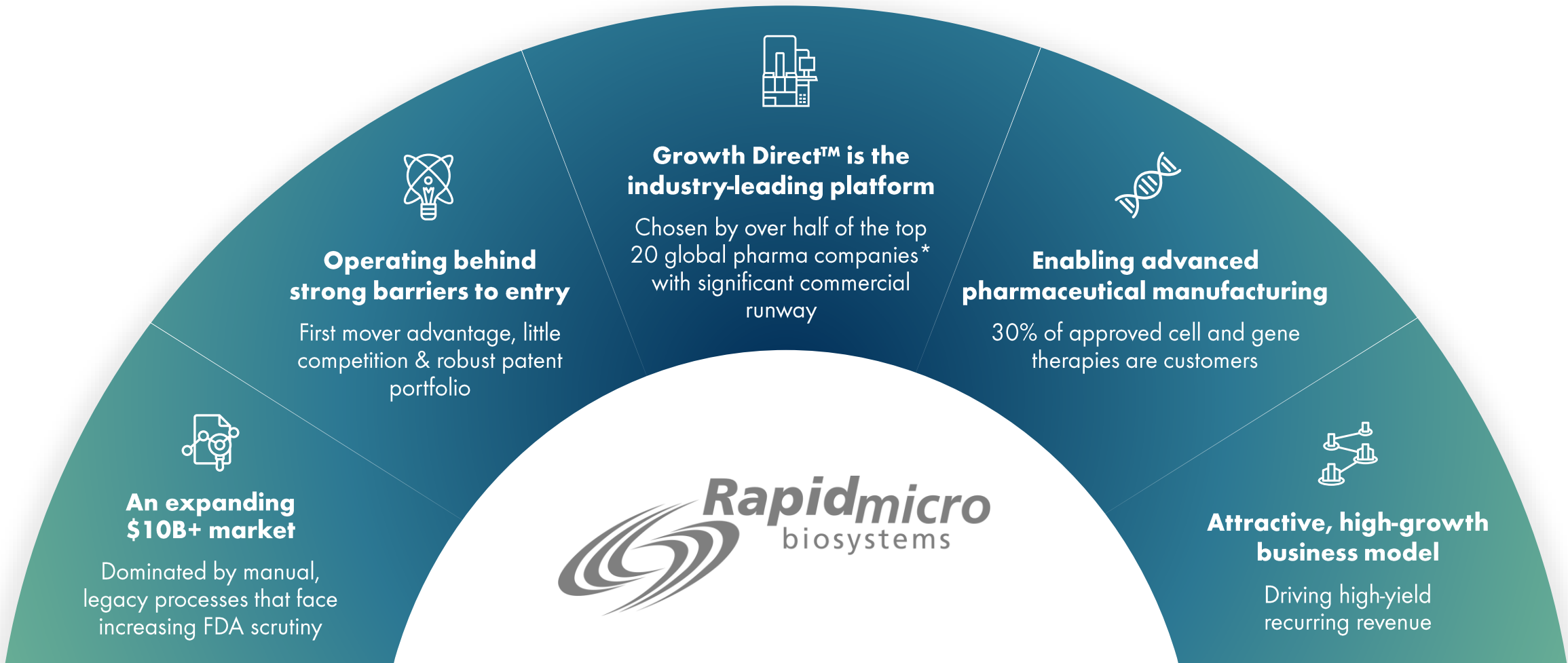
**\$10**  
BILLION

+

**\$8**  
BILLION

TAM  
EXPANSION





Rapid Micro Biosystems is creating the future of rapid, secure microbial quality control automation to enable advanced pharmaceutical manufacturing



## Legacy MQC

VS

## Growth Direct

MANUAL	.....	AUTOMATED
15 STEPS	.....	2 STEPS
5-14 DAYS TO RESULT	.....	50%+ FASTER
UNSECURED / REGULATORY RISK	.....	DATA INTEGRITY ENABLED





# Today's MQC labs utilize antiquated manual testing practices

## High-Volume Manual Testing

MQC ensures the final product is safe through the continuous testing of raw materials, the production environment, and the product itself for microbial contaminants

## FDA Mandated

MQC testing is required by the FDA and other global regulatory agencies for all pharmaceutical products

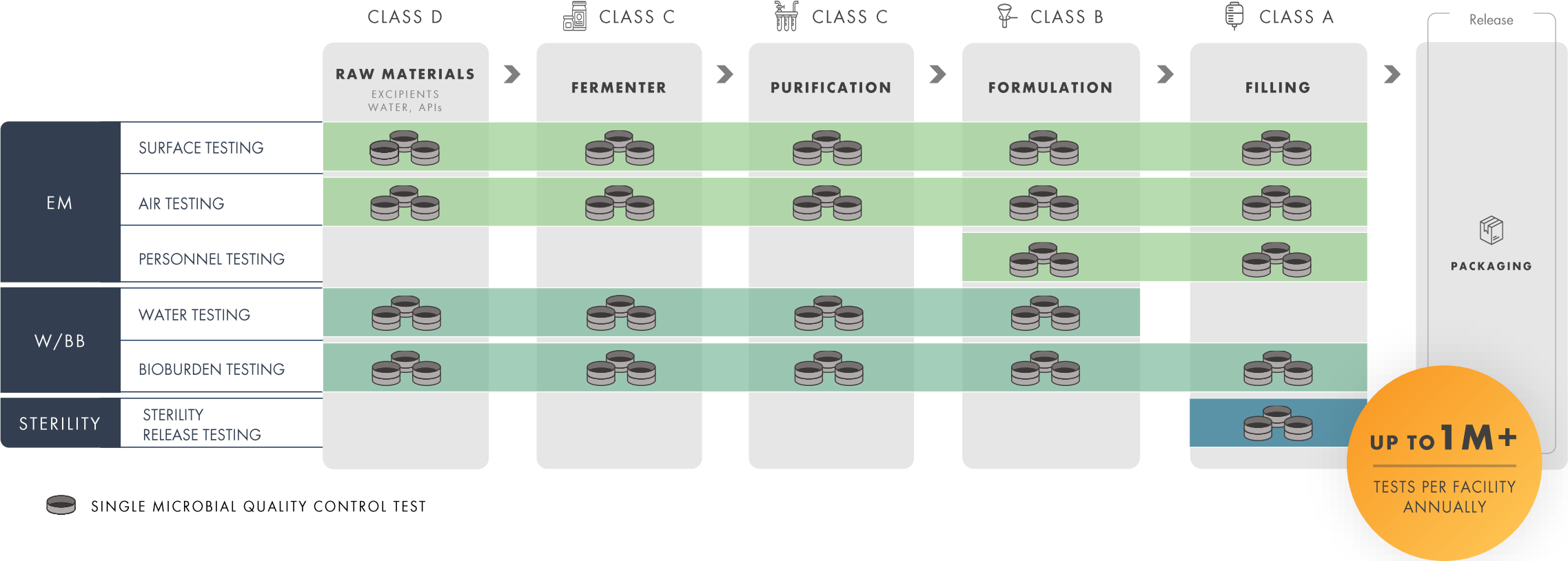
## Laborious, Slow and Subject to Human Error

MQC testing is currently conducted in centralized labs using laborious and inefficient manual workflows



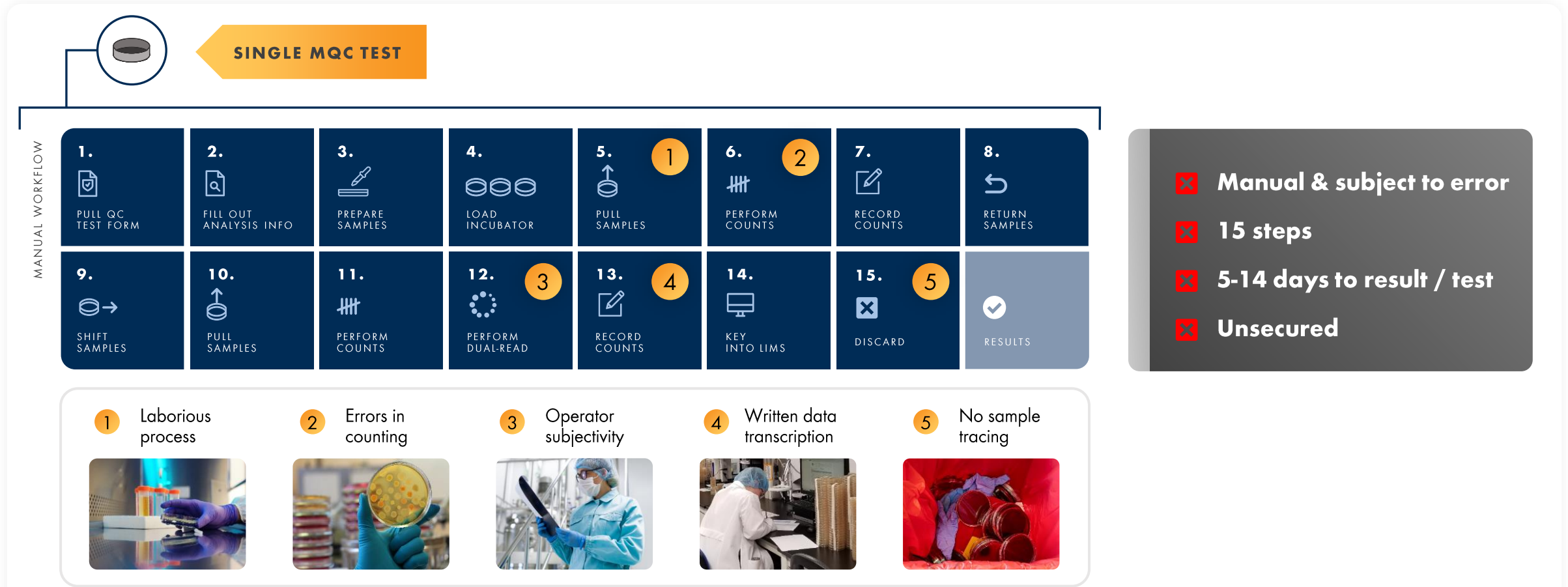


# MQC is pervasive throughout pharmaceutical production



MQC testing is constantly performed at high volumes throughout production to maintain quality control

# Every single MQC test poses multiple costs, risks and failure points



Multiplied at scale, manual MQC is vastly inefficient and costly

# Outdated MQC processes are costing organizations

Lapses in legacy MQC processes increase cost, regulatory scrutiny, and organizational risk



## FDA enforcement actions

such as 483s, warning letters and consent decrees



## 40-50%

of all warning letters issued globally contain a data integrity component



## 6-24 months

to resolve FDA 483s and investigations



## Up to \$100M

annual product loss per company due to MQC issues



## Billions of dollars

in potential shareholder value destruction due to MQC issues

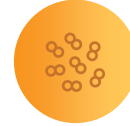
Potential risks have elevated MQC testing to the C-suite



# Persistent industry tailwinds further drive need for automated MQC



Increasing regulatory scrutiny and enforcement around **data integrity and quality**

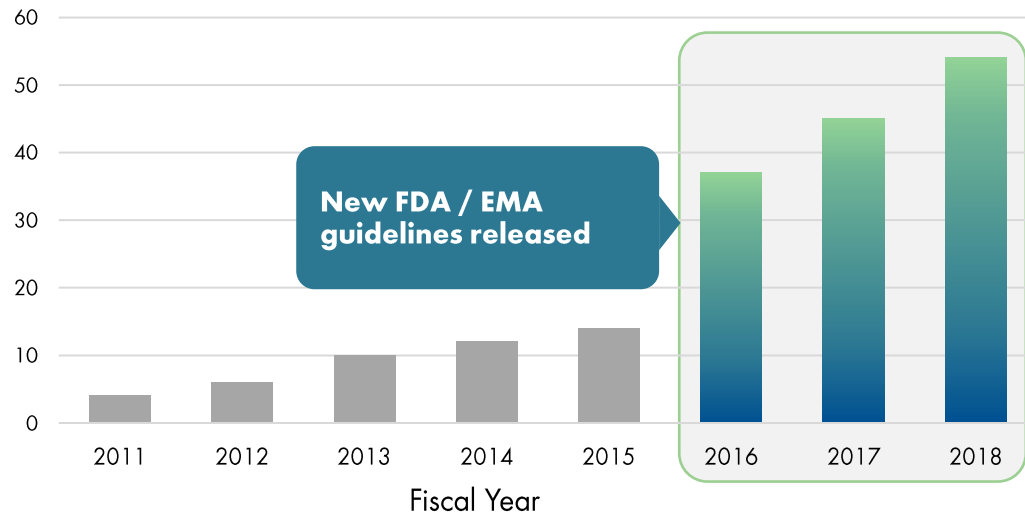


Growth in complex biologics, cell, and gene therapies which require **faster, more accurate, higher throughput testing capabilities**

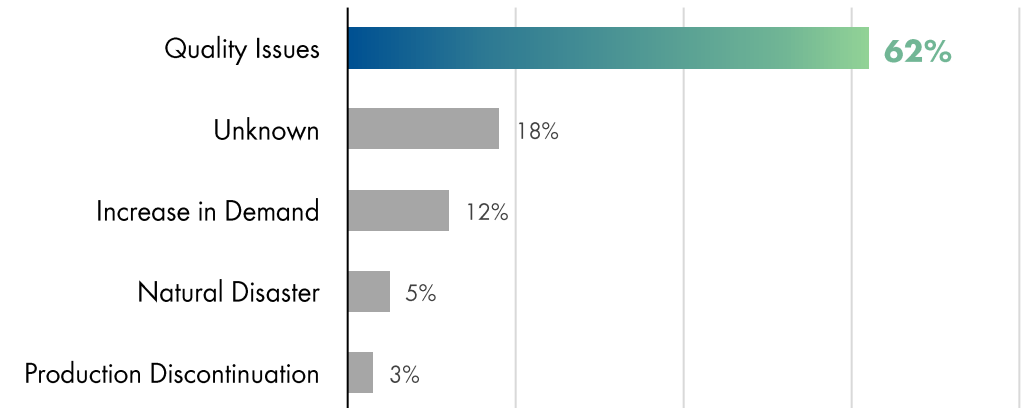


Significant global demand for drugs colliding with supply chain disruptions to **drive need for improved quality**

FDA WARNING LETTERS ISSUED DUE TO DATA INTEGRITY FINDINGS



PERCENTAGE OF DRUGS IN SHORTAGE BY REASON (CY 2013-2017)



# Introducing a revolution in MQC

FACTORS DRIVING CHANGE

SCIENTIFIC AND TECHNOLOGY INNOVATION

GROWING DEMAND FOR MORE COMPLEX THERAPIES

FASTER & LEANER MANUFACTURING

DATA INTEGRITY & SECURITY FOCUS

REGULATORY SCRUTINY

TODAY

DISCOVERY & RESEARCH



HIGH-THROUGHPUT R&D AUTOMATION



TODAY

QC & ANALYSIS



TODAY

BIOPROCESSING & MANUFACTURING



FLEXIBLE SINGLE USE TECHNOLOGIES



# The Growth Direct™ System

The future of microbial quality control

## FACTORS DRIVING CHANGE

SCIENTIFIC AND  
TECHNOLOGY  
INNOVATION

GROWING DEMAND FOR  
MORE COMPLEX  
THERAPIES

FASTER & LEANER  
MANUFACTURING

DATA INTEGRITY &  
SECURITY FOCUS

REGULATORY  
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TODAY

DISCOVERY  
& RESEARCH



HIGH-THROUGHPUT R&D AUTOMATION

TODAY

QC & ANALYSIS



TODAY

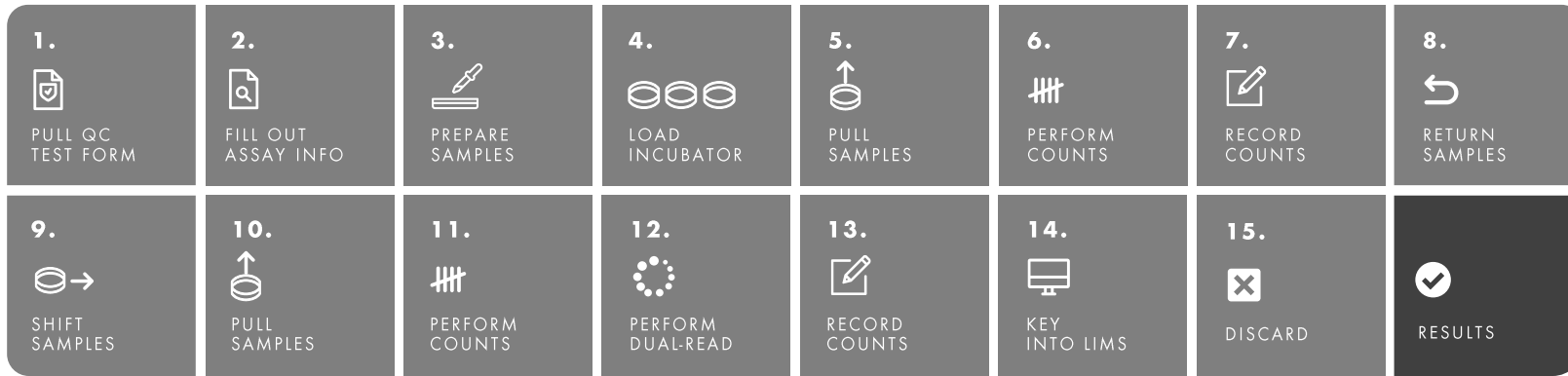
BIOPROCESSING  
& MANUFACTURING



FLEXIBLE SINGLE USE TECHNOLOGIES

# Growth Direct™ transforms and modernizes MQC

MANUAL WORKFLOW



- Manual & subject to error**
- 15 steps**
- 5-14 days to result / test**
- Unsecured**

## GROWTH DIRECT

AUTOMATED WORKFLOW



- Automated & accurate**
- 2 steps**
- Results in half the time**
- Full data integrity**

# Growth Direct's compelling value proposition is driving rapid global adoption



## Data Integrity



Secure critical data to ensure **global quality** and **regulatory compliance**



## Operational Efficiency



Deliver faster automated results for **improved decision making** and **business performance**



## Insight & Accuracy



Eliminate human quality control errors and **reduce business risk**



# Our robust business model generates multiple and recurring revenue streams



## Growth Direct

Purpose-built high-throughput MQC automation



## Proprietary Consumables

- Broad application suite
- Environmental monitoring
- Water
- Bioburden



## Global Validation & Support Services

Full installation, validation and maintenance services



## Data & Software

Two-way LIMS interface enabling fully paperless workflow

# Strong commercial traction driving our business growth

**116**

**CUMULATIVE SYSTEMS PLACED<sup>1</sup>**

**>1 million**

**CUMULATIVE CONSUMABLES SHIPPED**

**~60%**

**CUSTOMERS WITH MULTIPLE SYSTEMS**

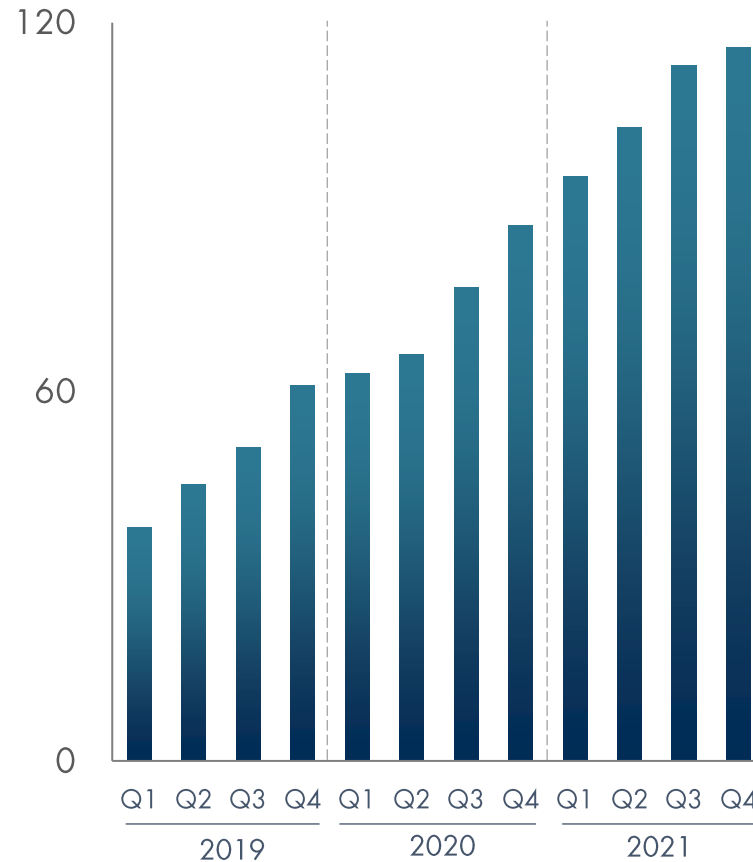
**~50%**

**CUSTOMERS WITH SYSTEMS IN MULTIPLE SITES**

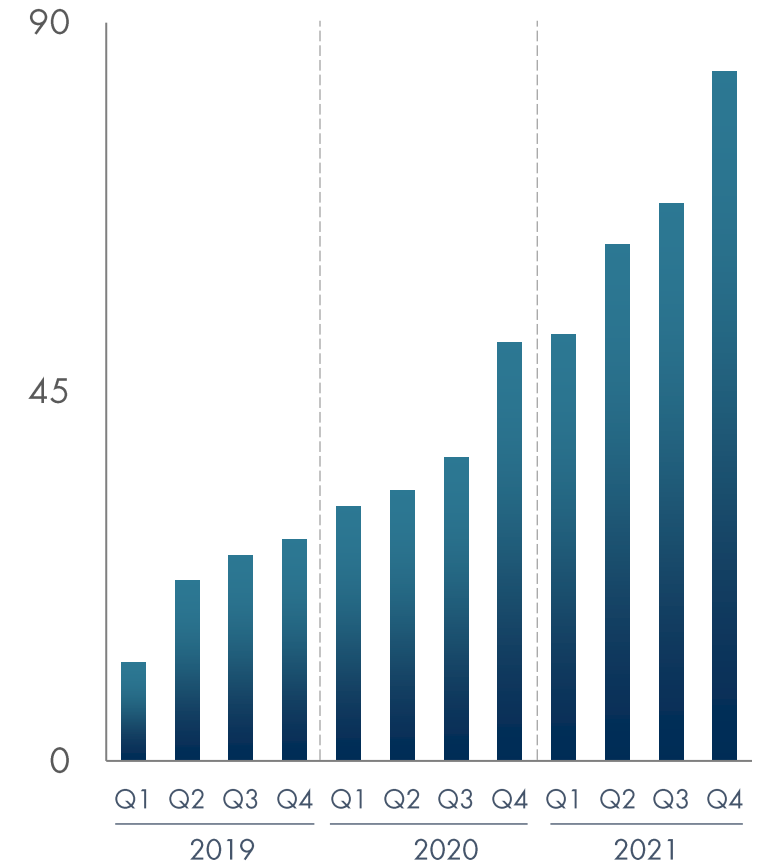
**>50%**

**OF TOP 20 GLOBAL PHARMA<sup>2</sup> ARE CUSTOMERS**

CUMULATIVE SYSTEM PLACEMENTS<sup>3</sup>



CUMULATIVE SYSTEMS VALIDATED<sup>3</sup>



1 As of 12/31/2021  
 2 By revenue  
 3 Includes systems sold prior to 2019

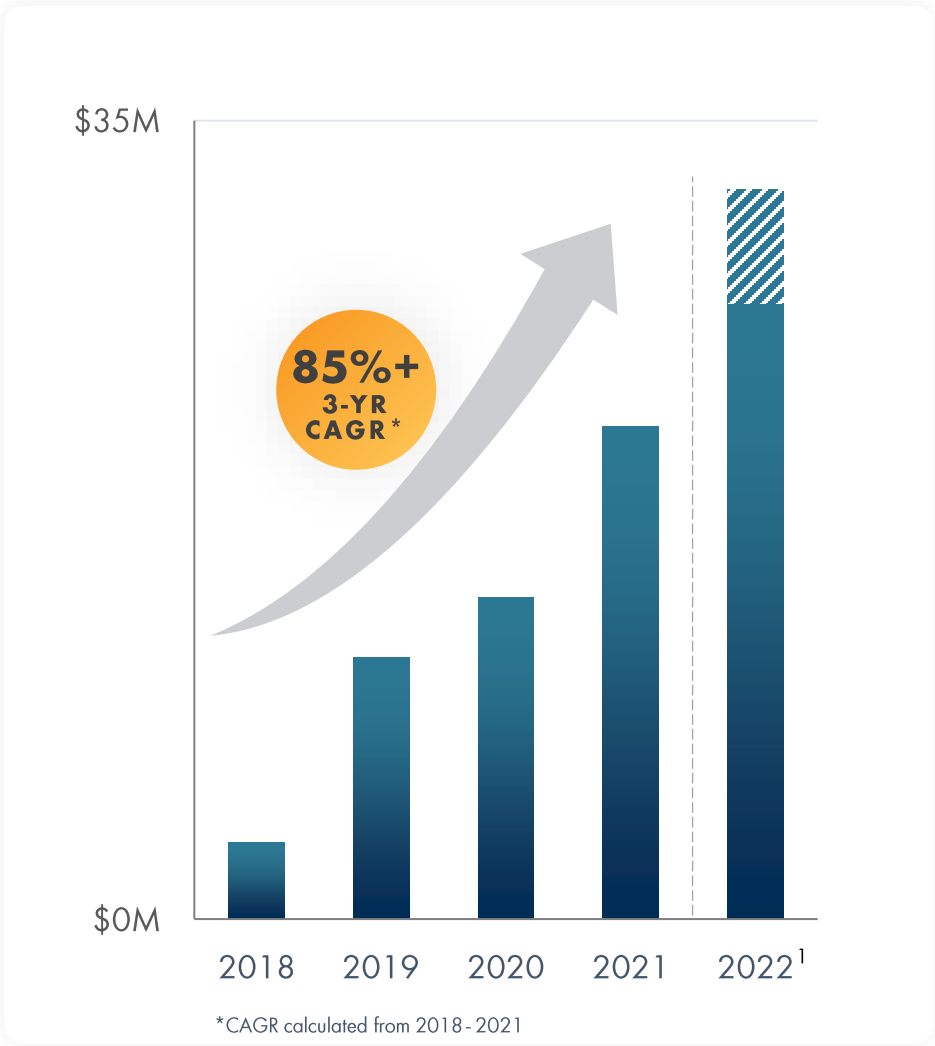


# Commercial Financial Summary

In \$M (unaudited)	Q4		FY	
	2020	2021	2020	2021
Product Revenue	\$4.1	\$2.9	\$11.0	\$15.5
Service Revenue	\$1.0	\$2.0	\$3.1	\$6.1
Commercial Revenue	\$5.1	\$4.9	\$14.1	\$21.6
<b>Year-over-Year Growth</b>		<b>(5)%</b>		<b>54%</b>
Gross Margin % - Commercial	(57)%	(54)%	(56)%	(36)%
Operating Expenses	\$6.6	\$12.0	\$22.5	\$39.5
Loss from Operations	\$(9.7)	\$(14.6)	\$(30.5)	\$(47.2)



# Commercial revenue growth



In Millions (unaudited)	2020	2021	2022 <sup>1</sup>
Recurring Revenue	\$3.9	\$7.8	
<b>YoY Growth<sup>2</sup></b>	<b>105%</b>	<b>100%</b>	
Non-Recurring Revenue	\$10.2	\$13.8	
<b>YoY Growth<sup>2</sup></b>	<b>10%</b>	<b>36%</b>	
Commercial Revenue	\$14.1	\$21.6	\$27.0 - \$32.0
<b>YoY Growth<sup>2</sup></b>	<b>30%</b>	<b>54%</b>	<b>25% - 50%</b>

1 Guidance reaffirmed March 4, 2022  
2 Approximate

# Strategic opportunity to own the QC & Analysis workflow

## QC & ANALYSIS

WORKFLOW (PREP TO ANALYSIS)



DISCOVERY & RESEARCH

PROCESS DEVELOPMENT

BIOPROCESSING / MANUFACTURING

CLINICAL / DIAGNOSTIC

ThermoFisher  
SCIENTIFIC



charles river



charles river

ThermoFisher  
SCIENTIFIC

MILLIPORE  
SIGMA



sartorius

ThermoFisher  
SCIENTIFIC



Widespread adoption of automation,  
high degree  
of organized competition

Widespread adoption of automation,  
high degree  
of organized competition

**Establishing the new standard in  
QC & Analysis**

# Rapid Micro Biosystems (RMB)

## Investment Highlights

- Growing **\$10 billion+ market** under pressure to automate and modernize
- **Proprietary technology** platform with **captive ecosystem** offering best-in-class automated and secure MQC testing
- **First mover advantage and little competition** bolstered by investment and patent-protected innovation across multiple technology disciplines
- Chosen by over half of the **top 20 global pharma** companies\* with significant growth potential
- Deep integration into heavily regulated advanced pharmaceutical manufacturing processes, especially bioprocessing of **biologics, cell and gene therapies**
- Highly attractive business model leveraging growing installed base of systems to generate **high-yield recurring revenues**
- Exciting product development and market opportunities to **significantly expand our TAM**
- **Experienced management team** and workforce with deep domain knowledge

# APPENDIX



# Fourth Quarter and Full Year 2021 Financials and Key Performance Indicators

In thousands (unaudited)	Three Months Ended Dec. 31			Twelve Months Ended Dec. 31		
	2021	2020	Growth	2021	2020	Growth
Product Revenue	\$2,882	\$4,071	-29%	\$15,512	\$10,992	41%
Service Revenue	\$1,973	\$1,031	91%	\$6,125	\$3,091	98%
<b>Commercial Revenue</b>	<b>\$4,855</b>	<b>\$5,102</b>	<b>-5%</b>	<b>\$21,637</b>	<b>\$14,083</b>	<b>54%</b>
Non-Commercial Revenue	\$353	\$136	160%	\$1,595	\$1,994	-20%
<b>Total Revenue</b>	<b>\$5,208</b>	<b>\$5,238</b>	<b>-1%</b>	<b>\$23,232</b>	<b>\$16,077</b>	<b>45%</b>

	Three Months Ended Dec. 31			Twelve Months Ended Dec. 31		
	2021	2020	Growth	2021	2020	Growth
Recurring Revenue	\$2,283	\$1,196	91%	\$7,819	\$3,908	100%
Non-Recurring Revenue	\$2,572	\$3,906	-34%	\$13,818	\$10,175	36%
<b>Commercial Revenue</b>	<b>\$4,855</b>	<b>\$5,102</b>	<b>-5%</b>	<b>\$21,637</b>	<b>\$14,083</b>	<b>54%</b>
Non-Commercial Revenue	\$353	\$136	160%	\$1,595	\$1,994	-20%
<b>Total Revenue</b>	<b>\$5,208</b>	<b>\$5,238</b>	<b>-1%</b>	<b>\$23,232</b>	<b>\$16,077</b>	<b>45%</b>

	Three Months Ended Dec. 31			Twelve Months Ended Dec. 31		
	2021	2020	Growth	2021	2020	Growth
Systems Placed	3	10	-70%	29	26	12%
Cumulative Systems Placed	116	87	33%	116	87	33%
Validations Completed	16	14	14%	33	24	38%
Cumulative Validations Completed	84	51	65%	84	51	65%