

Review of Current Worldwide Microbiology Testing Methods and Markets in Pharmaceutical Manufacturing

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INTRODUCTION

Testing for microbiological safety is a fundamental practice in any parental pharmaceutical manufacturing practice. Because of the importance of this testing and the overall size of the worldwide parental pharma manufacturing market, the volume of testing completed is large and the supply of the materials for this testing is consequently a large and significant market.

Strategic Consulting, Inc. collected primary data on the number and types of tests conducted worldwide, including interviews and electronic surveys from pharmaceutical facilities in North America, Europe, Latin America and Asia (incl. India and China). The market was validated as consisting of a worldwide test volume of 415 million tests and a market value for test materials of \$1.64 billion.

Market Facts

2018 Market Value	\$ 1.6 Billion
2018 Test Volume	415 Million
2023 Projected Value	\$ 2.1 Billion
2023 Projected Test Volume	526 Million
2018 - 2023 CAGR – Value	5.2%
2018 - 2023 CAGR – Volume	4.9%

PROJECT BACKGROUND

To develop this market data, in 2017 and 2018 Strategic Consulting collected data from more than 300 pharmaceutical companies worldwide including facilities in each of the three major world regions (North America, Europe and Asia/Rest of World – and including facilities in India and China). The data was gathered through electronic surveys, telephone and email interviews using a preset questionnaire. The questions focused on volumes of microbiological tests conducted, parameters and organisms tested for, the detection/test methods used in the analysis and reasons for the test volume and methods selected.

MARKET DEFINITION

Strategic Consulting defines the worldwide pharma sector as including approximately 5,400 plants with 25 or more employees. Our research project focused only on these facilities and did not attempt to collect data from smaller facilities. These facilities were found to conduct an average of approx. 77,000 tests per year, with a very wide range in test volumes with smaller facilities that may collect "thousands" of tests per year to the largest pharma plants that collect more than 1 million tests per year.

MARKET DATA

The worldwide Pharma Sector has shown steady growth in test volume from 105 million tests when we first examined the market in 1993 to 206 million tests in 2003, 348 million tests in 2014 to our current 2018 estimated volume of 415 million tests. This growth is expected to continue at a slightly faster growth rate and reach 526 million tests in 2023.

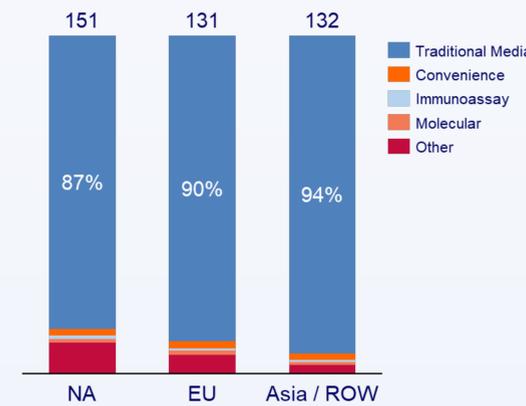


The market value of Industrial Microbiology testing in the Pharma Sector has gained steadily from US\$ 365 million (USD) to nearly US\$ 995 million in 2008, US \$1.360 billion and now reaching over US\$1.640 billion in 2018. With a slightly decreasing rate of growth expected, the Pharma Sector should reach an estimated US \$2.1 billion in market value by 2023.



TEST METHODOLOGY VOLUME AND TARGETS

Pharma continues to rely primarily on traditional media-based methods for most testing. This was found to be the case in our survey and confirmed to be relatively unchanged over the past 10 years. Traditional methods decreased only slightly in volume share from 98.5% in 2008 to 92.8% in 2014, to approx. 90% in 2018, and are expected to show only a slight continued decline to approx 88 - 89% in 2023. This change is attributable to the growth of other methods, rather than reductions or conversions from traditional growth methods.



Pharma Test Methods - Worldwide (2018)

North America (NA) has the highest regional test volume with approx. 151 million total tests in 2018. NA will continue to be the leading sector in test volume through the end of the forecast period with 187 million tests in 2023. Due to the rapid growth or production in the region, Asia/ROW has overtaken Europe as the second largest by volume with 132 million tests and forecasted to grow to 177 million tests in 2023 with Europe (EU) accounting for 131 million tests in 2018 growing to approximately 162 million tests in 2023.

Asia/ROW will continue to grow more rapidly and is expected to continue to grow significantly in the future, with both enormous potential internal demand and expanding capabilities for pharmaceutical manufacturing. We estimate that Asia/ROW will have the largest share of test volume mid next decade.

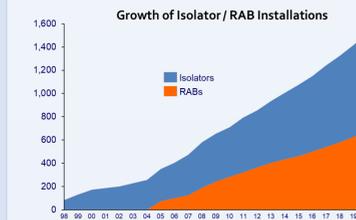
As evidence of this growth, the US FDA reports that they conduct approx. 10,000 inspections in facilities world-wide. FDA data further shows that the number of sites inspected have grown only ~3% in the US and 16% in the EU, respectively between 2011 and 2016, while growth of facilities inspected in India and China, for example increased ~55% and ~63%, respectively in that same time period.

The survey data showed that two types of tests - Total Viable Organisms (TVO / Bioburden) and "Specialty Other Micro" tests - which include tests for targets such as endotoxin, mycoplasma and viruses - are the top two largest test categories by volume. Tests for endotoxin are a large portion of this category and showed slightly higher growth rates than the overall market (approx. 1pt higher than the market volume rate) while tests for other targets have remained in-line with market growth.



It is expected that TVO/bioburden tests for environmental monitoring (surfaces, air, personnel, equipment, water), raw materials, in-process and final non-sterile products will continue to be the dominant type of testing performed for the foreseeable future. There will likely be reductions in the rate of growth of environmental monitoring test volume as more manufacturing moves to RABs and Isolators.

TOPICAL ISSUES AFFECTING TESTING



Isolators / RABs

The increased use of Isolators and RABs will change the volume of environmental monitoring in pharma, placing less emphasis on monitoring of cleanrooms.

Biologics / Genomics Therapies

Growth in the production of biologic therapies will increase the level of end-product testing as these drugs are not typically terminally sterilized. These drugs are also typically produced in small batches increasing sample turnover collected by batch.

Asia

The rapid growth of pharmaceutical manufacturing in Asia, specifically in China and India, will increase demand for microbiological testing. Many of these facilities will also use cleanrooms increasing demand for EM testing.

CONCLUSIONS

Microbiological test volume and market value in pharmaceuticals has continued to show steady growth for the past 20 years. This 18-month project conducted in 2017 and 2018 confirms that this growth is expected to continue at roughly the same rates through 2023 creating a worldwide market encompassing an estimated 526 million tests with a market value of \$2.1 billion. While this market will continue to grow in every region, a significant portion of the growth will come from Asia as that region's pharmaceutical manufacturing capacity grows more rapidly. This will increase the rate of growth of test volume but will add pressure on test pricing as increased demand attracts new competition and especially new entrants from Asia who will increase overall competition in that region and throughout the world.

REFERENCES

Industrial Microbiology Market Report – 5th Edition, Strategic Consulting, 2018

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