

*STRIVING TO DELIVER EXTRAORDINARY RESULTS*

# OQSIE OVERVIEW

Operations & Quality Systems Improvement Experts

 Irvine, California

 [www.oqsie.com](http://www.oqsie.com)

Certified Minority Owned Small Business

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Small Business

 Headquartered in  
**Southern California**

 Serving  
**The Americas, Europe,  
and Asia**

 **Pharmaceutical**

 **Biotechnology**

 **Vaccines**

 **Consumer Health Products**

 **Animal Health**

 **Medical Devices**

 **Vitamins and Nutritionals**

# HOW WE HELP OUR CLIENTS

*OQSIE is an execution-based consulting company with a focus in Life Sciences, helping clients since 2013.*

We're the premier problem-solvers supporting the industry, offering the highest value at the lowest cost. *We have deep expertise in **Manufacturing, Quality Assurance, Regulatory Compliance, Supply Chain** and **Operational Excellence**, and support leaders in these functions through our four business segments below.*

- ❖ **Quality & Compliance**
- ❖ **Performance Improvement**
- ❖ **Technology (Pharma 4.0) Solutions**
- ❖ **Workforce Solutions**



# QUALITY & COMPLIANCE

*We help leaders stay ahead of quality and compliance issues in addition to leading and supporting remediation activities. Our capabilities include:*

## **Quality Management Systems Gap Assessments**

We identify common issues, gaps and opportunities for improvement across multiple regulatory and operational dimensions with advanced analytics.

## **Compliance Remediation**

Our expertise includes remediation program structure and launch, 3<sup>rd</sup> party document reviews, and quality system remediation activities.

## **Bridging Capacity & Capability Gaps**

Our consultants play roles such as Quality Engineers, Deviation Investigators, CAPA SMEs, Change Control SMEs, Complaint Investigators, Method Validation SMEs, Sterility Assurance SMEs, and Technical Writers.

## **Audits**

We supplement audit teams with experienced consultants and provide the technology to perform effective remote audits.

In addition, we offer Quality 4.0 solutions, outlined on **slide 5**.



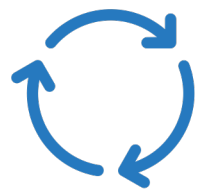
# PERFORMANCE IMPROVEMENT

Our team consists of top-tier consultants as well as industry experts that play roles as:

- ✓ Lean Six-Sigma Subject Matter Experts
- ✓ Project Managers
- ✓ Program Management Office Professionals



We work seamlessly with client staff as a single, integrated team.



We focus on building your team's capabilities and skills to ensure improvements are sustainable over time.

Clients leverage **our deep functional expertise** and **broad geographical reach**.

## ***Our problem-solving experts specialize in:***

- ❖ Product and Process Capability
- ❖ Reduction of Process Variability
- ❖ Multi-Variate Statistical Analysis
- ❖ Structured Problem Solving
- ❖ Quality Operations
- ❖ Regulatory Compliance
- ❖ Inventory & Service Level Optimization
- ❖ Productivity/Throughput Improvement

## ***Our core competencies include:***

- ❖ Operational Performance
- ❖ Program & Project Management
- ❖ Risk Management
- ❖ Compliance Remediation
- ❖ Cost Reduction
- ❖ Supply Chain Optimization
- ❖ Technology Transfer

# TECHNOLOGY (PHARMA 4.0) SOLUTIONS

Our ***predictive-analytics*** based solutions are made to improve performance and productivity in Supply Chain, Quality Assurance, and Manufacturing operations.

## Our cost-effective solutions can be implemented as a suite or individually:

- ❖ Supply Chain App
- ❖ Production Scheduling App
- ❖ Distribution Center Operations App
- ❖ Overall Equipment Effectiveness App
- ❖ Quality Investigations App
- ❖ Continuous QMS Health Monitoring



Quick 2-3 month implementation time – minimal resources required.



Connect and integrate data from all available resources (MES, ERPs, QMS, LIMS, spreadsheets, etc.).



A real-time management dashboard to track progress and status, tailored for each role.



Automated alerts through text/email when issues are predicted or beginning to arise.

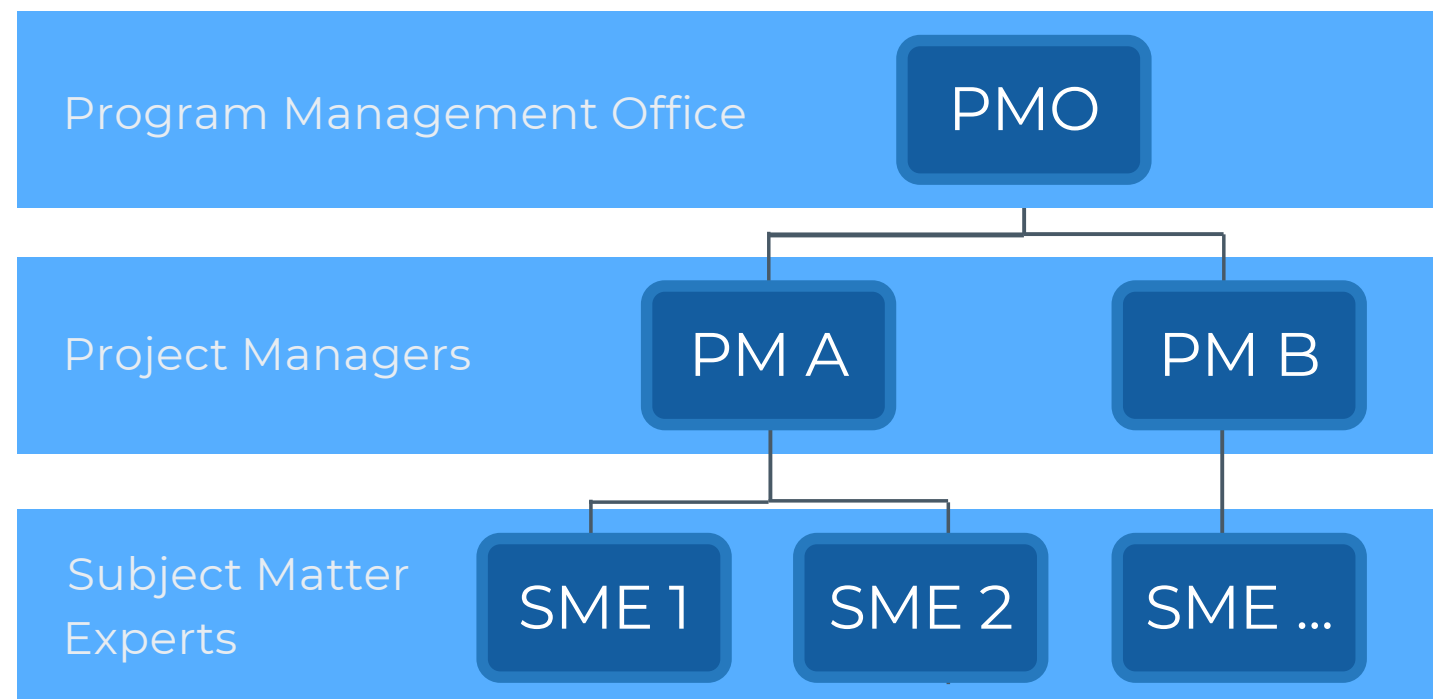


*We guarantee, in writing, that clients will recover their small investment in the first year, and that software license fees will be covered by tangible cost reductions of at least 4 times larger.*



# WORKFORCE SOLUTIONS

Our team helps companies resolve short or long term capacity or capability gaps with highly skilled and experienced consultants through **Statement of Work** projects.



Clients leverage our carefully selected, high caliber **“doers”**.

## We have deep expertise in:

- ❖ Quality Assurance
- ❖ Compliance
- ❖ Validation
- ❖ Manufacturing
- ❖ Supply Chain

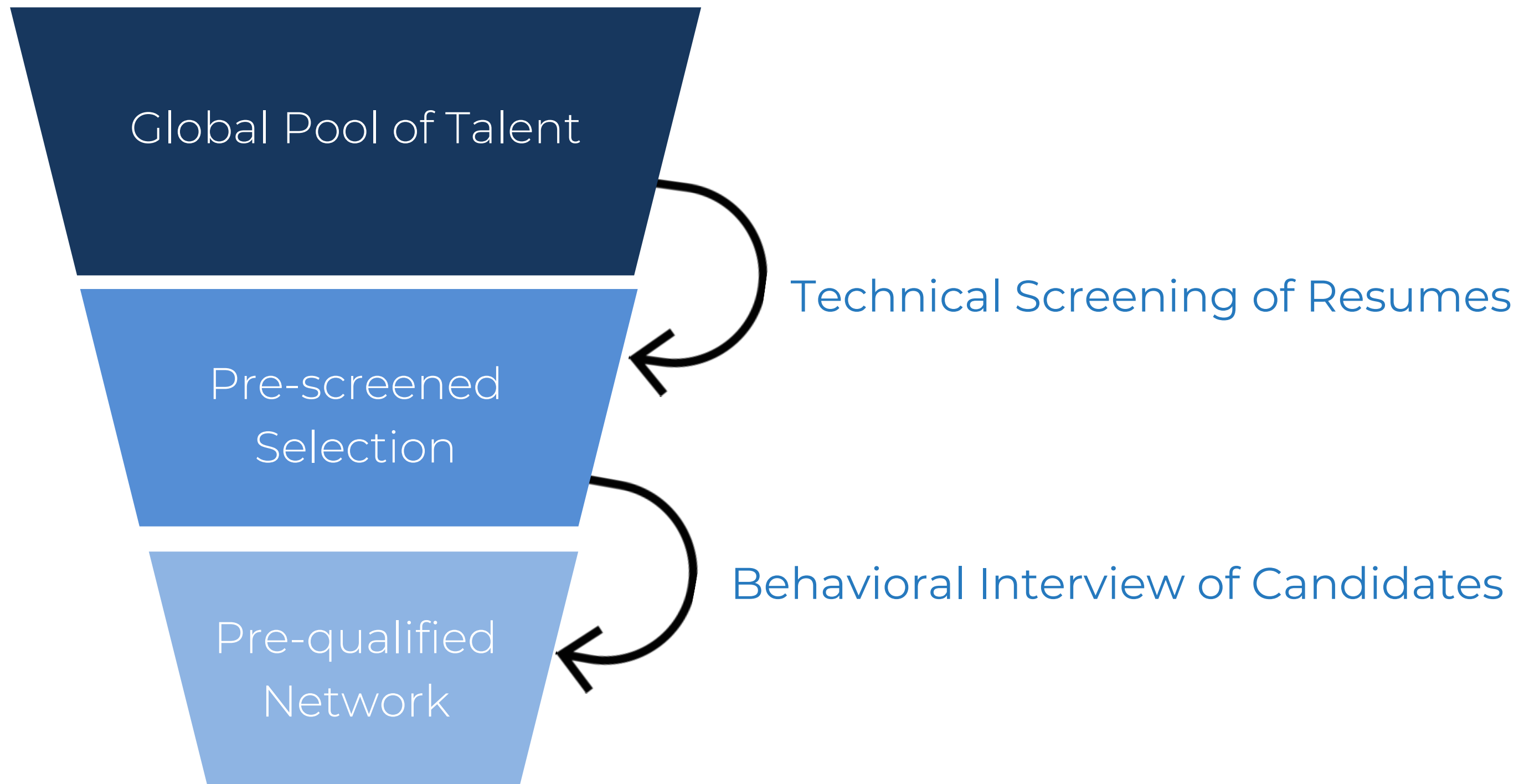
## Roles that we often support:

- ❖ Project & Program Managers
- ❖ Quality System Investigators
- ❖ CAPA Engineers
- ❖ Validation & Reliability Engineers
- ❖ QC/Laboratory Experts
- ❖ Document Review Specialists
- ❖ Quality Engineers
- ❖ Technical Writers
- ❖ Change Control SMEs
- ❖ Sterility Assurance SMEs



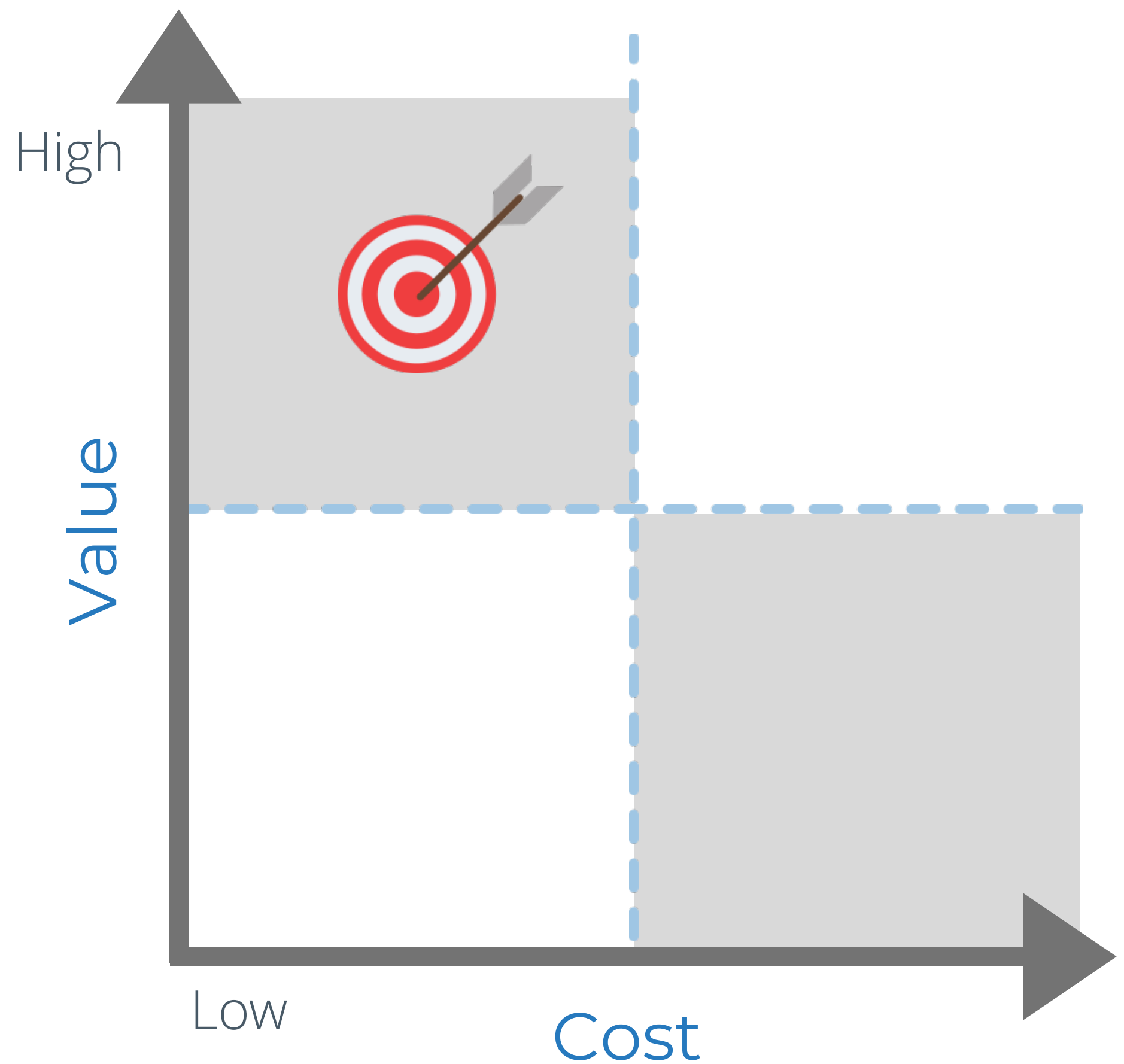
# Methodical Recruiting and Selection Process

*Proven ability to identify and assess high caliber professionals*



# OUR VALUE PROPOSITION IS SIMPLE

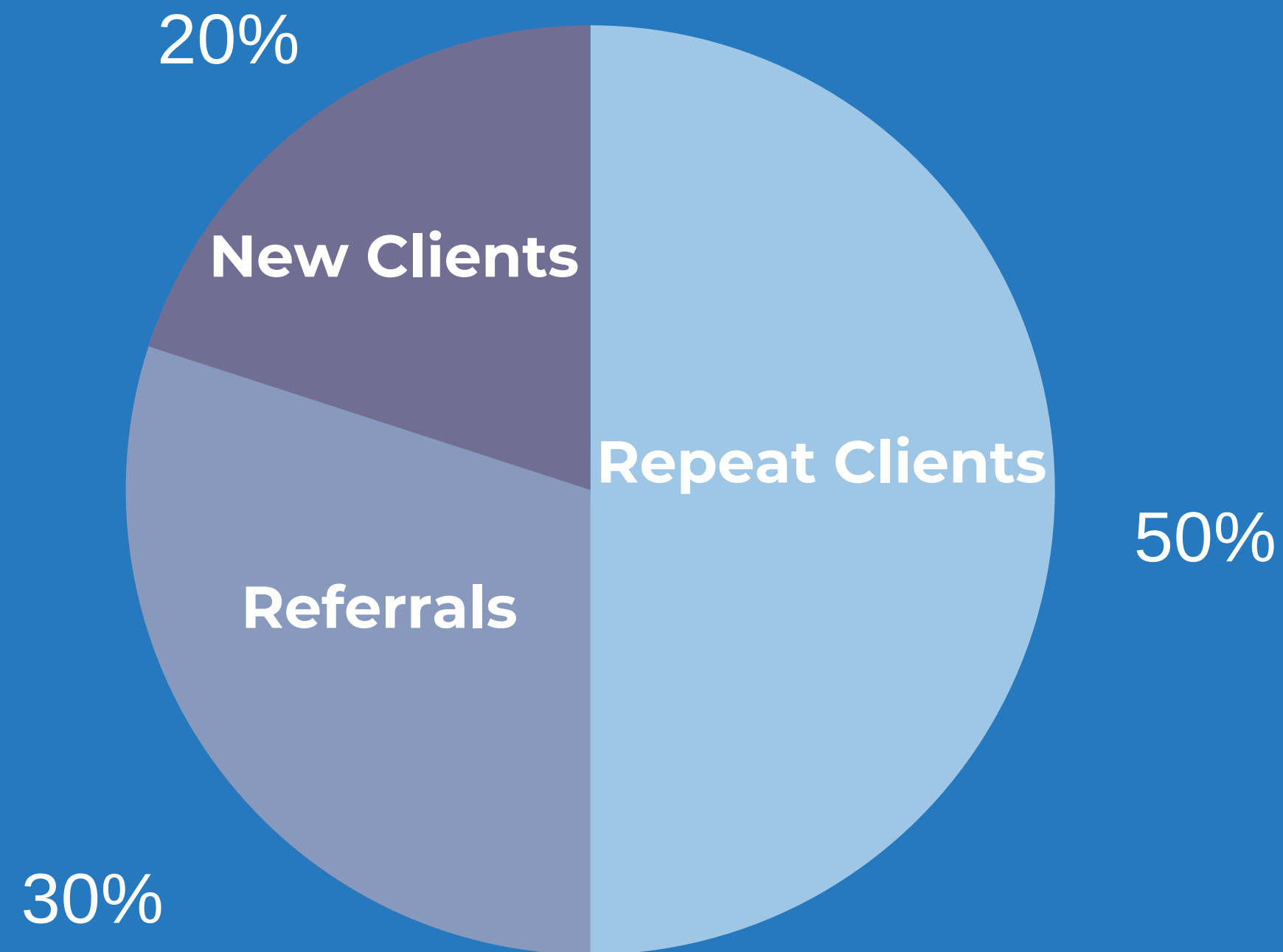
*We offer the best value for our client's money in the industry.*





# Satisfied Clients

*More than **80%** of clients are repeat clients or referrals.*





# HOW CAN WE HELP YOU?

Contact:

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