



COMMISSIONING & QUALIFICATION

Applying industry best practices to reduce
ramp up time and improve quality

A global partner in providing professional services to enhance
operational performance and reliability.





COMMISSIONING & QUALIFICATION

Capital Project Delivery

CAI helps our customers design, deliver, operate, and maintain quality manufacturing or mission-critical facilities. Our engineering, technical, and consulting services encompass all aspects of operation: equipment, automation, process, and human performance. We are the leading independent commissioning and qualification firm with the most experience implementing ASTM E2500. The result is a superior level of operational performance and reliability.

People | Process | Product

Our clients' focus is on bringing lifesaving medicines to patients; reducing total life-cycle costs, all while meeting the demands of global GMP regulations. We execute our clients' vision, delivering efficient, reliable, GMP-compliant facilities and processes. We enable our clients to reach the higher standard expected of GMP operations today.

Meeting the Challenge of Global GMP-Regulated Manufacturing

We help you meet the challenges of manufacturing high quality products using a focus on the product lifecycle — from rapid delivery of novel life-saving therapies to adapting to challenging cost structures. Our professionals work with you, helping you to be more competitive as you meet the demands of a global patient population.

Professional Services:

- ASTM E2500 – Risk based verification programs
- Concept design studies
- Technology transfer planning and project management
- Regulatory strategy development
- Commissioning, qualification, and validation (CQV) master planning
- CQV planning, preparation, and execution
- Process quality risk assessments
- Project planning: scheduling, budgeting, and reporting
- Operational readiness
- Owner project management



Qualification and Validation Services

GMP project delivery is a demanding endeavor. Our skilled and well-managed teams, using our proven GMP information management software, are the right choice for your project. We can support your most complex large-scale capital projects, as well as your small critical retrofit/expansion ones. This enables you to reach a higher standard while reducing your risk. Let us help you meet the most stringent quality, cost, and schedule requirements.

Technical Services:

- Design review/qualification
- FAT/ SAT planning and execution support
- Commissioning protocol development and field execution
- Facility and process startup support
- IQ/OQ/PQ protocol development and execution
- Process validation support
- Cleaning validation
- Shipping validation
- Disposables validation
- Automation qualification
- Computer systems validation

CAI Benefits

Partnering with us allows our clients to more readily achieve operational efficiency, lifecycle management, high product yields, superior quality, and lower cost of goods. We do this by implementing a regimented “right the first time,” lean approach.

This systematic approach is built into our company culture, and has proven to meet the challenges of regulatory compliance, supply chain assurance, production availability, equipment reliability, and maintenance of high quality standards.

Our owner-employees are trained and qualified to deliver to exacting quality standards while managing cost, schedule, and scope. Our talented staff, innovative tools, and culture of excellence get you to production quickly and with minimum delays.

The Right Partner

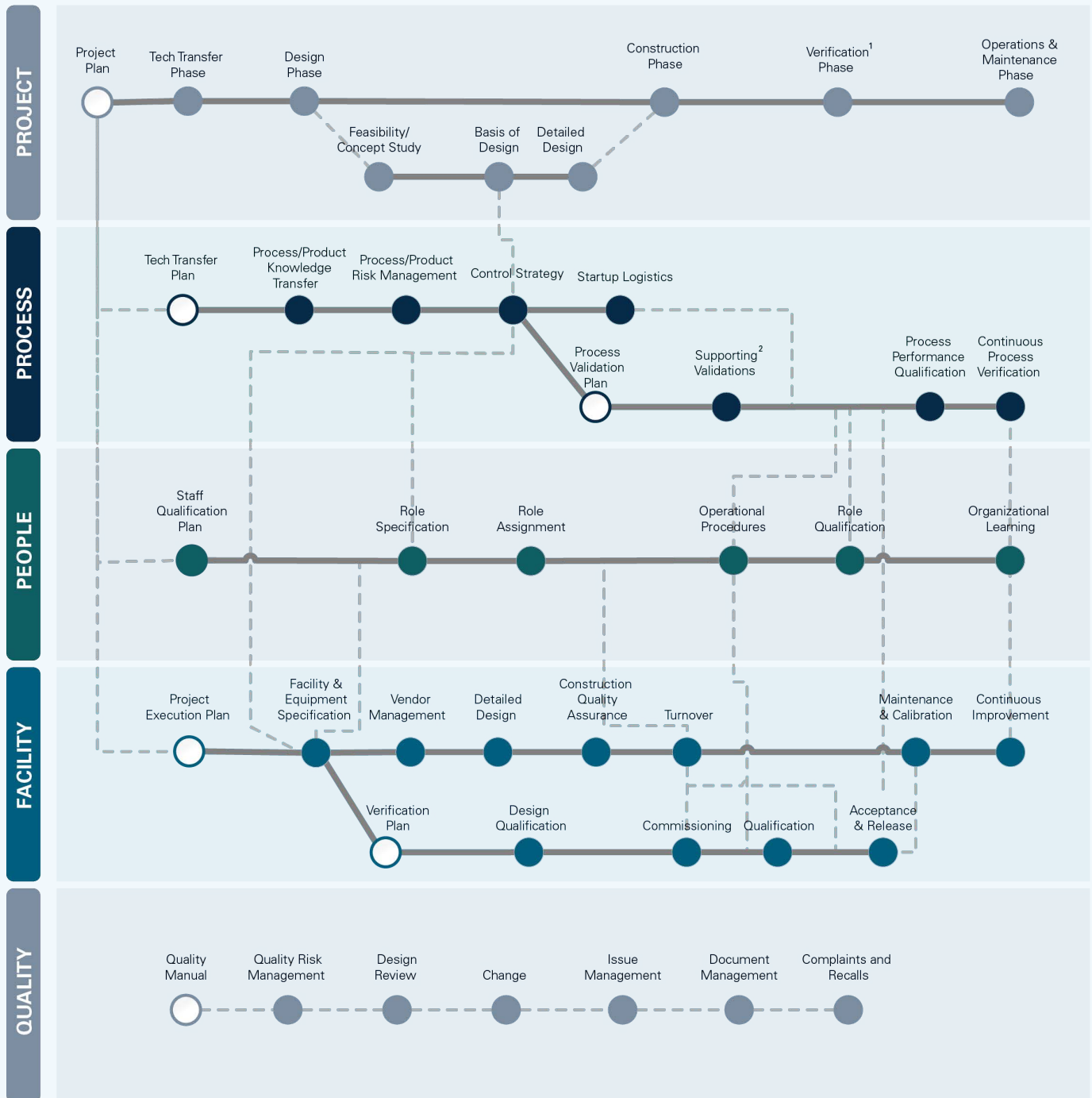
We deliver knowledge, industry leadership, innovative approaches, and a unique GMP information management suite. All of which are designed to focus on your needs.

Our teams work to meet a higher standard of project execution, GMP services, and professional services to achieve operational reliability and performance in a cost-effective and compliant manner.

We have delivered services to more than 500 customers globally. We have the financial strength and scale to execute your project wherever it is. Our dedicated teams are focused on helping you achieve your goals and delivering high quality, lifesaving products to patients.



Manufacturing Delivery



¹ Verification Phase includes all test phases and activities including factory testing, site testing, commissioning and qualification.

² Supporting Validations include analytical methods, materials, cleaning and transportation.

Technologies and Sectors Include:

- Biotechnology
- Aseptic manufacturing – fill finish
- Small-molecule
- Active pharmaceutical ingredients (API)
- Oral solid dosage
- Parenteral manufacturing
- Medical devices
- Combination products
- Critical facilities
- Novel technologies (e.g. gene therapy and personalized medicine)

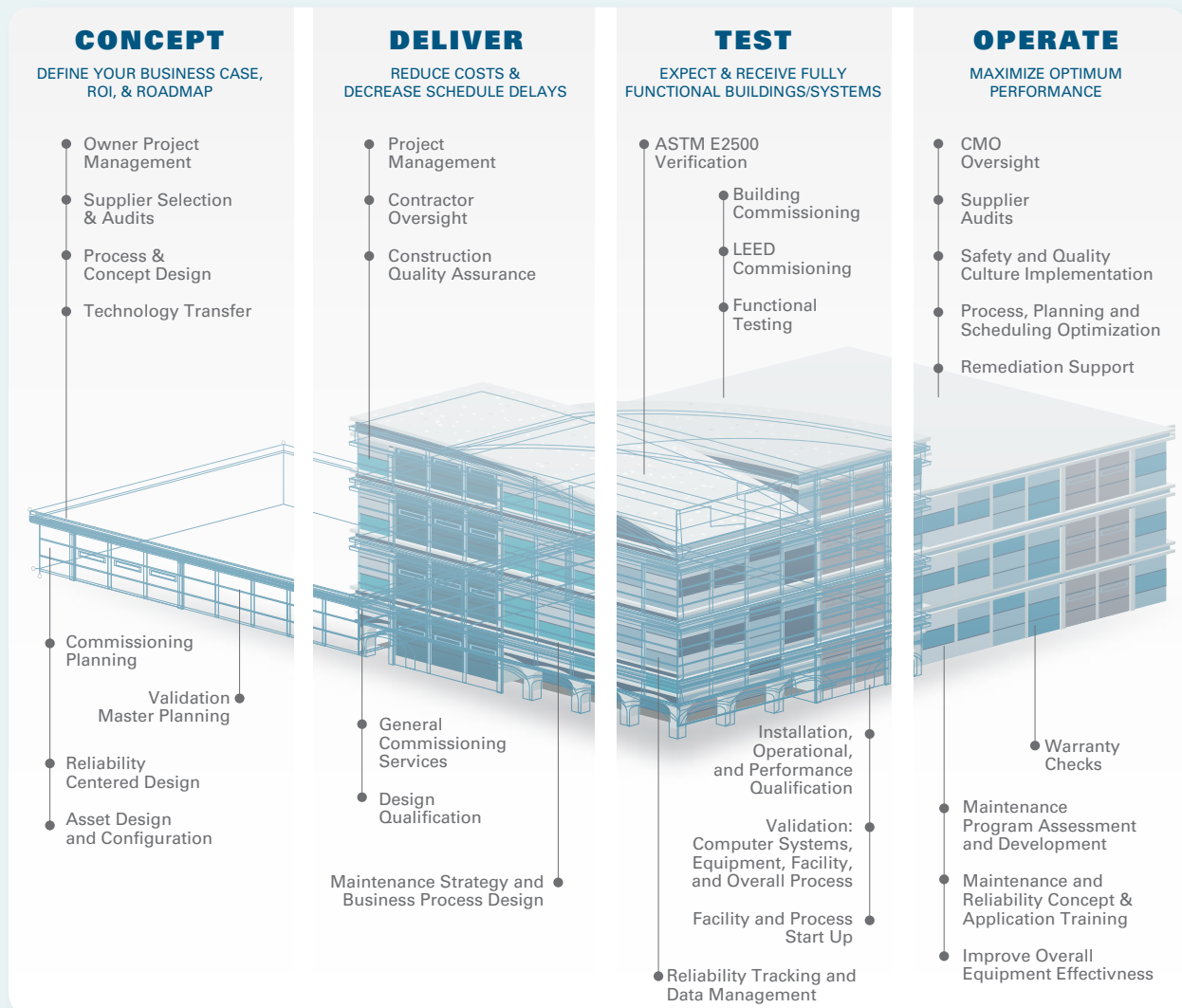
Reaching Higher Standards for Global GMP-Regulated Manufacturing

We help you meet the challenges of manufacturing high quality products – rapid delivery of novel life-saving therapies and shrinking cost structures to satisfy the demands of a global patient population.

We understand how to integrate the people and the process to produce GMP-quality products. Our professional and technical services are focused on the performance and reliability of GMP manufacturing operations. From concept design, process control strategy, commissioning, and validation to full-scale, compliant operations, we facilitate project and facility delivery.



Global Project Delivery




Commissioning & Qualification

 Building Commissioning

 Asset Management & Reliability

 Quality, Compliance, & Regulatory

 Human Performance

 Process & Manufacturing Technologies

 Program & Project Management

 Automation & Information Technology

 The Chemistry of Full-Scale Operations™

CAI

One Park Fletcher
2601 Fortune Circle East, Suite 301B
Indianapolis, IN 46241 USA
PHONE: +1 317-271-6082
EMAIL: cai.admin@cagents.com

Commissioning Agents Puerto Rico LLC

District View Plaza
644 Fernández Juncos Avenue
San Juan, Puerto Rico 00907-3122
PHONE: +1 787-919-7323
EMAIL: cai.admin@cagents.com

Commissioning Agents International Singapore Pte Ltd

1 Maritime Square
+09-57 Harbourfront Centre
Singapore 099253
PHONE: +65 6252 5850
EMAIL: seasia.admin@cagents.com

Commissioning Agents Ireland Ltd

Unit K28, Drinan Enterprise Centre,
Swords Enterprise Park, Swords,
Co. Dublin, Ireland, K67 NH96
PHONE: +353 (0) 1 892 80 90
EMAIL: european.admin@cagents.com

CAI (Shanghai) Engineering Technical Consulting Co., Ltd

Room 358, Business Mansion,
Shanghai Exhibition Center
No. 1333 West Nanjing Road
Jing'an District, Shanghai 200040, China
PHONE: +86 21 6016 7577
EMAIL: china.admin@cagents.com

CAI Technical & Consulting (Malaysia) SDN. BHD.

14th Floor, Menara Keck Seng
203 Jalan Bukit Bintang
55100 Kuala Lumpur, Malaysia
PHONE: +65 6252 5850
EMAIL: seasia.admin@cagents.com



WHEN YOU NEED TO MEET A HIGHER STANDARD™

+1 317-271-6082 • cagents.com