CiVentiChem

Simple Solutions for Complex Chemistry

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About Us

CiVentiChem is an ISO certified Company, which has been providing simple solutions for complex chemistry problems for 30 years to pharmaceutical, biotech and other life sciences companies worldwide

As a global Contract Research, Development and Manufacturing company, CiVentiChem has maintained its emphasis on providing simple solutions to complex chemistry problems with excellent customer service

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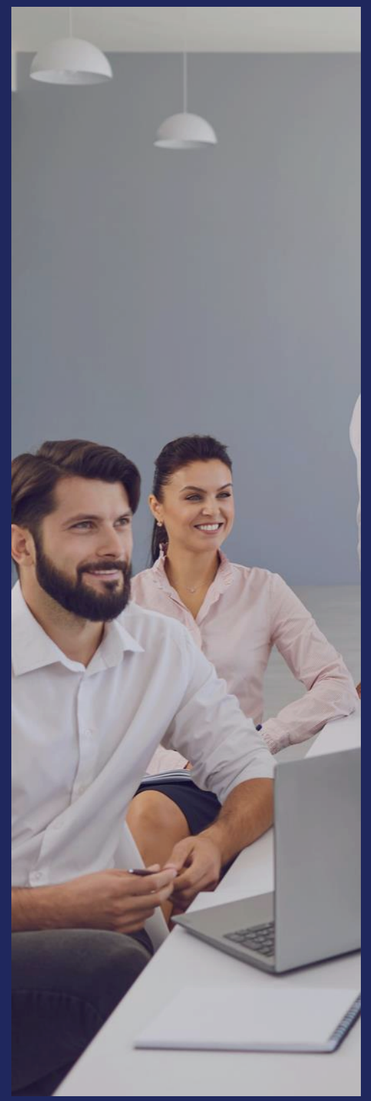

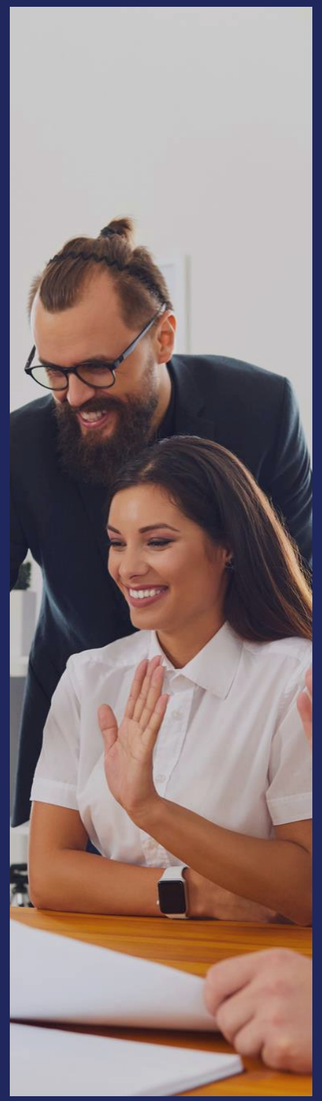

Our Vision

To be a world class trusted partner delivering simple solutions to complex chemistry problems

Our Mission

To Develop, Demonstrate & Manufacturing of Advanced Intermediates, Speciality Chemicals & APIs with Quality and Commitment

Company Profile

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OUR JOURNEY

1994 — FOUNDED in RTP, North Carolina (USA)

1999 — Expanded to Larger Laboratory

2011 — Established cGMP Facility at NC site

2019 — CiVentiChem US site was acquired by Sterling - UK

2001 — Established R&D Facility in Hyderabad

2009 — Launched Manufacturing plant in Hyderabad

2019 — Acquired Large-Scale Manufacturing plant in Choutuppal, Telangana

2024 — cGMP Facility will be operational from Jan’24

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Company Overview

Founded - 1994

Our People

- 150+ Global Head count
- 50 Research Chemists
- 7 Ph.D Scientists

1,50,000 sq.ft

Total Technical space

- **Headquarters & Sales Office** : Cary, NC (USA)
- **R&D, & Manufacturing Unit-I :** Hyderabad, India
- **Manufacturing Unit-II :** Choutuppal, Telangana, India
- **ISO Certified** - ISO 9001, ISO 14001, ISO 45001
- **PMDA Japan** Approved facility for Intermediates

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EXECUTIVE MANAGEMENT

Bhaskar Venepalli, Ph.D., MBA, FRSC.
Co-Founder, CEO & President

Dr. Venepalli has over 35 years of experience working with fine chemicals. Before co-founding CiVentiChem in 1994, he spent 13 years with Eastman Kodak. Received his Ph.D. from Osmania University, Hyderabad (India) and did Post Doctoral Research at the University of Southampton (England) & Rockefeller University (New York). He received his MBA from the Simon Business School at the University of Rochester. Dr. Venepalli is a Board Member of the North Carolina Biotechnology Center

Srinivas (Vasu) Chittineni, Ph.D.
Co-Founder & Managing Director

Dr. Chittineni has over 35 years vast experience in synthetic organic chemistry with expertise in Complex Organic Synthesis, Chiral and Carbohydrate Chemistry. He currently leads CiVentiChem's operations in Hyderabad, India. Dr.Chittineni received his Ph.D. from Kakatiya University (IICT, Hyderabad, India) and did his Post Doctoral Research at Duke University

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Key Services

Having vast experience over 30 years as a global CRAMS Company, CiVentiChem offers following Services to niche Biotechs, CDMO’s, Pharma, Crop sciences and other Fine chemical companies

Medicinal Chemistry

Process Development

Custom Manufacturing

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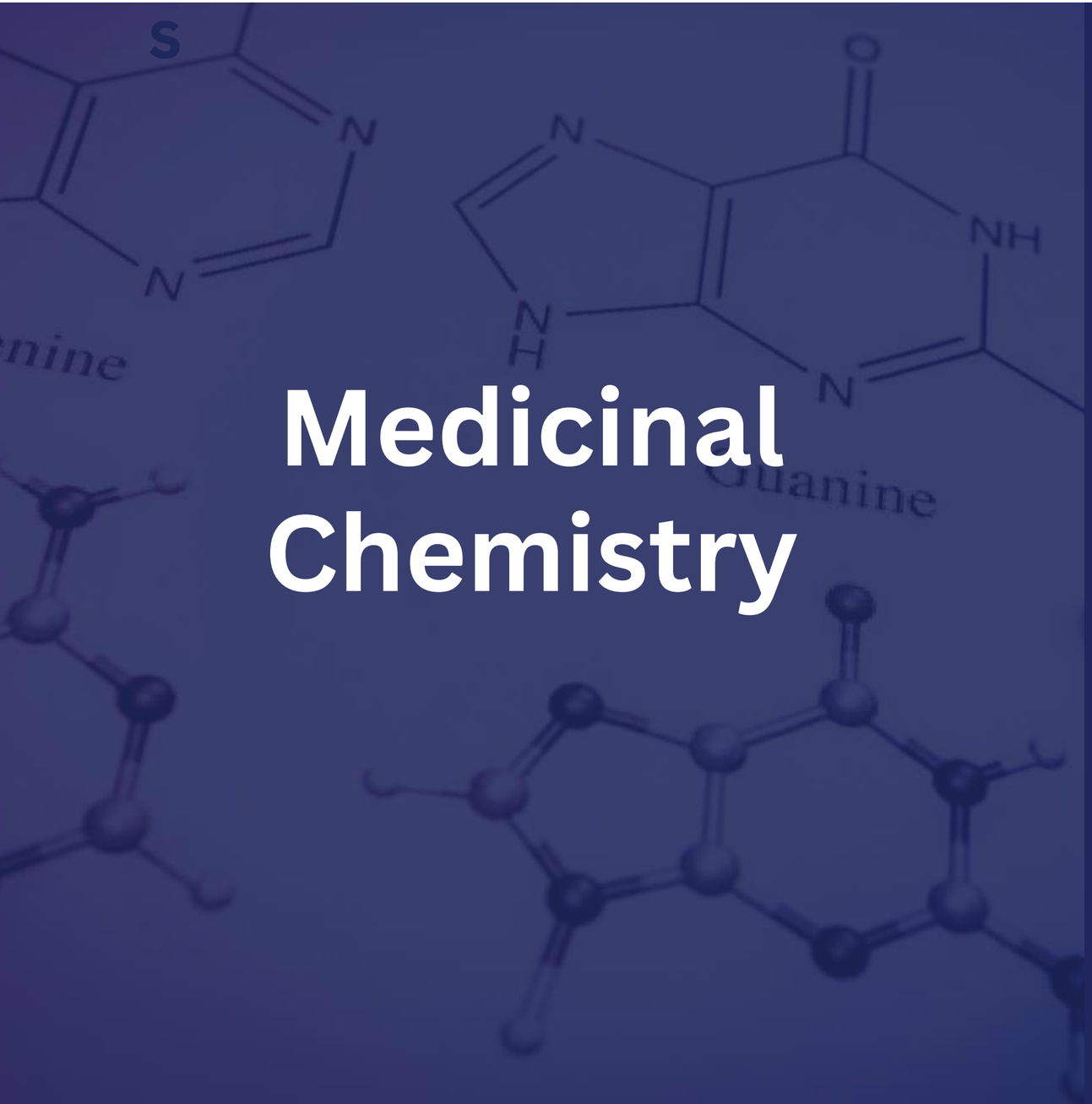

Medicinal Chemistry

- Drug discovery services including lead optimization and parallel synthesis
- Synthesis of NCE’s, focused libraries, building blocks and lead compounds
- Route scouting and synthesis of analogues
- Synthesis of reference standards, metabolites, impurities, and stable labeled compounds

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Process Development

- Identification and development of non-infringing process
- Optimization and scale-up of existing processes
- Developing new scalable and economically viable processes
- Process safety and Hazop studies
- Analytical Method Development
- Process Validation

Custom Manufacturing

- Rapid initial scale-up to first Kilogram
- Large scale manufacturing of complex intermediates, RSMs & Speciality chemicals (Kg to MT)
- Manufacturing of APIs
- Comprehensive Quality Management systems

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Chemistry Capabilities

- **General Reactions**
- **Grignard Reactions**
- **Halogenations (Cl / Br / I)**
- **Hydrogenation Reactions**
- **Enzymatic Resolutions**
- **Reactions in Aqueous medium**

- **Transition Metal Reactions**
  - Buchwald-Hartwig Coupling
  - Suzuki coupling
  - Negishi coupling
  - Sonogashira reaction
  - Stille Coupling

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Chemistry Expertise

- Carbohydrate Chemistry
- Reference standards & Stable Labeled compounds
- Chiral Catalysts and Reagents
- Alkyl Hydrazines & Cyanations
- Novel Heterocyclic compounds
- Chiral Binaphthols & Boronic Acids

Novel Hetero cyclic compounds for supporting all the stages in drug discovery & development :

Pyrazoles, Pyridines, Isoxasole, Oxazoles, Pyrazines, Pyridazines, Pyrimidines, Pyrrolo-pyrimidine, Azaindoles, Indazoles, Piperidino-pyrimidines and other complex Heterocylces

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Manufacturing Facilities

- CiVentiChem has two multi-purpose manufacturing facilities in Hyderabad (India)
- Over 40 reactors (SS, GLR & AGRs) having a capacity ranging from 100L to 4000L
- Overall Capacity of Unit-I : 15 KL and Unit-II : 45 KL
- Capable of operating -78°C to 200°C + temperature reactions
- Equipped with Zero liquid discharge (ZLD) and 40KL per day MEE plant
- CiVentiChem has all the necessary Statutory approvals from the government and the concerned authorities

Facilities & Capabilities

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Unit - I

- SS316 Reactor 2000L - 1
- SS316 Reactor 1600L - 1
- SS316 Reactor 1000L - 2
- SS316 Reactor 250L - 3
- SS316 Reactor 350L - 2
- SS316 Reactor 500L - 1
- Glass Lined Reactor 160L - 1
- Glass Lined Reactor 250L - 2
- Glass Lined Reactor 500L - 1
- Glass Lined Reactor 1000L - 1
- Glass Lined Reactor 1600L - 1
- Vacuum Tray dryer 6 Tray - 1
- Centrifuge SS316 36" - 1
- Centrifuge SS316 24" - 1
- Centrifuge SS316 18" - 1
- Centrifuge SS316 & halar coat 36" - 1
- FRP Reactor 2000L - 1
- Glass Lined Reactor 1600L - 1
- Glass Lined Reactor 630L - 1
- Glass Lined Reactor 100L - 1
- Hydrogenator - 1L/2 L/10 L Auto Clave - 1
- Tray dryer 12 trays - 1
- Tray dryer 24 Tray - 1
- Tray dryer 48 Tray - 1

Unit - II

- Glass Lined Reactor 1600L - 3
- Glass Lined Reactor 2000L - 1
- Glass Lined Reactor 3000L - 3
- SS316 Reactor 1000L - 1
- SS316 Reactor 1600L - 4
- SS316 Reactor 2000L - 3
- SS316 Reactor 3000L - 3
- Centrifuge SS316 36" - 1
- Centrifuge SS316 48" - 1
- Centrifuge Halar 48" - 1
- Tray dryer 96 trays - 2
- Nutsche filter 500 L - 1

Note - Both the units are well-equipped with all the necessary ancillary equipment

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Analytical Facilities

Unit - I

- HPLC With PDA detector - 4
- UPLC with PDA detector - 1
- HPLC with RI + VWD detector - 1
- LCMS (TOF) - 1
- GC with FID + TCD - 1
- GC-HS with FID - 1
- LCMS - 2
- UV - Spectrophotometer - 1

Unit -II

- HPLC With PDA detector - 1
- GC with FID - 1
- UV - Spectrophotometer- 1

Performance Metrics

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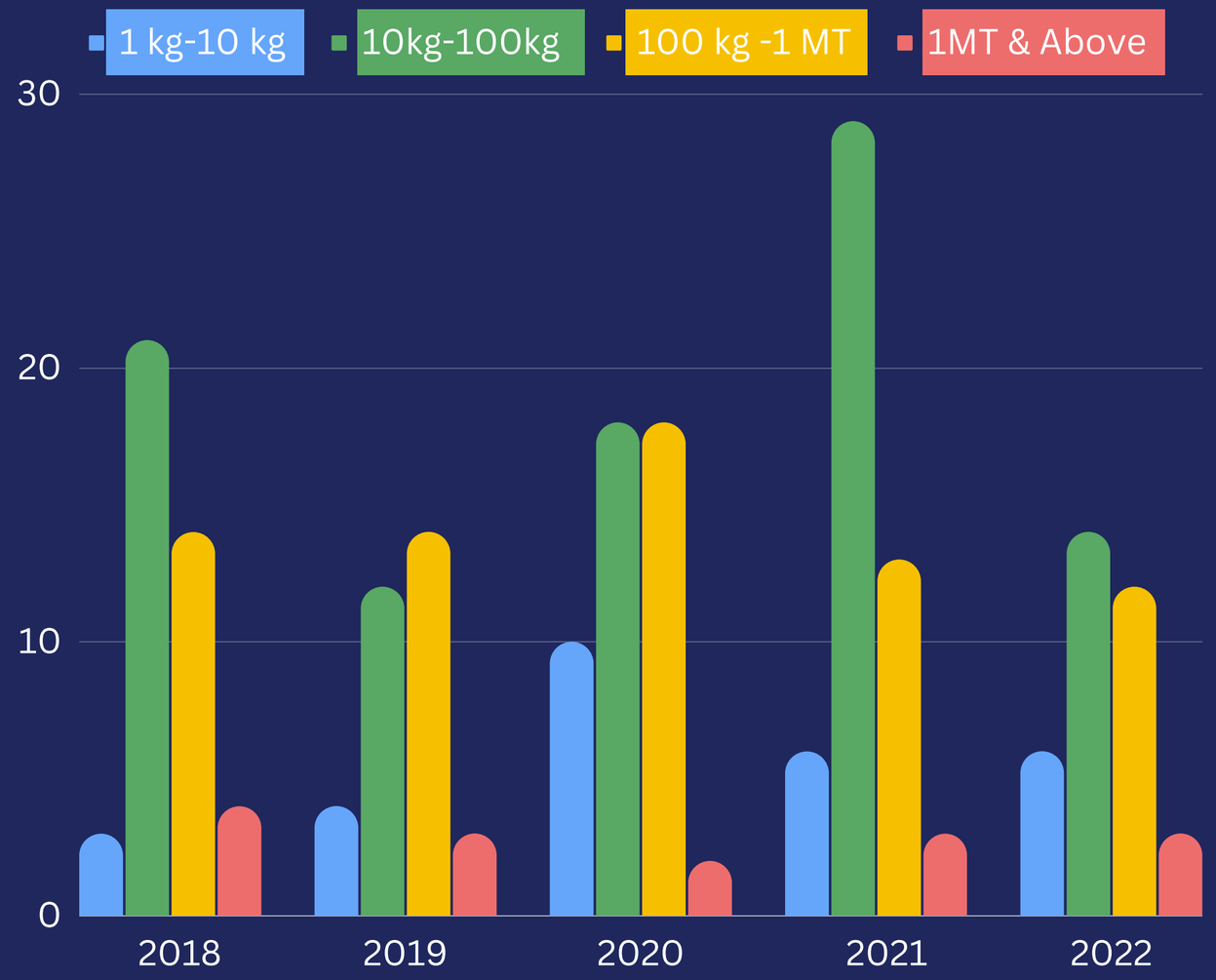
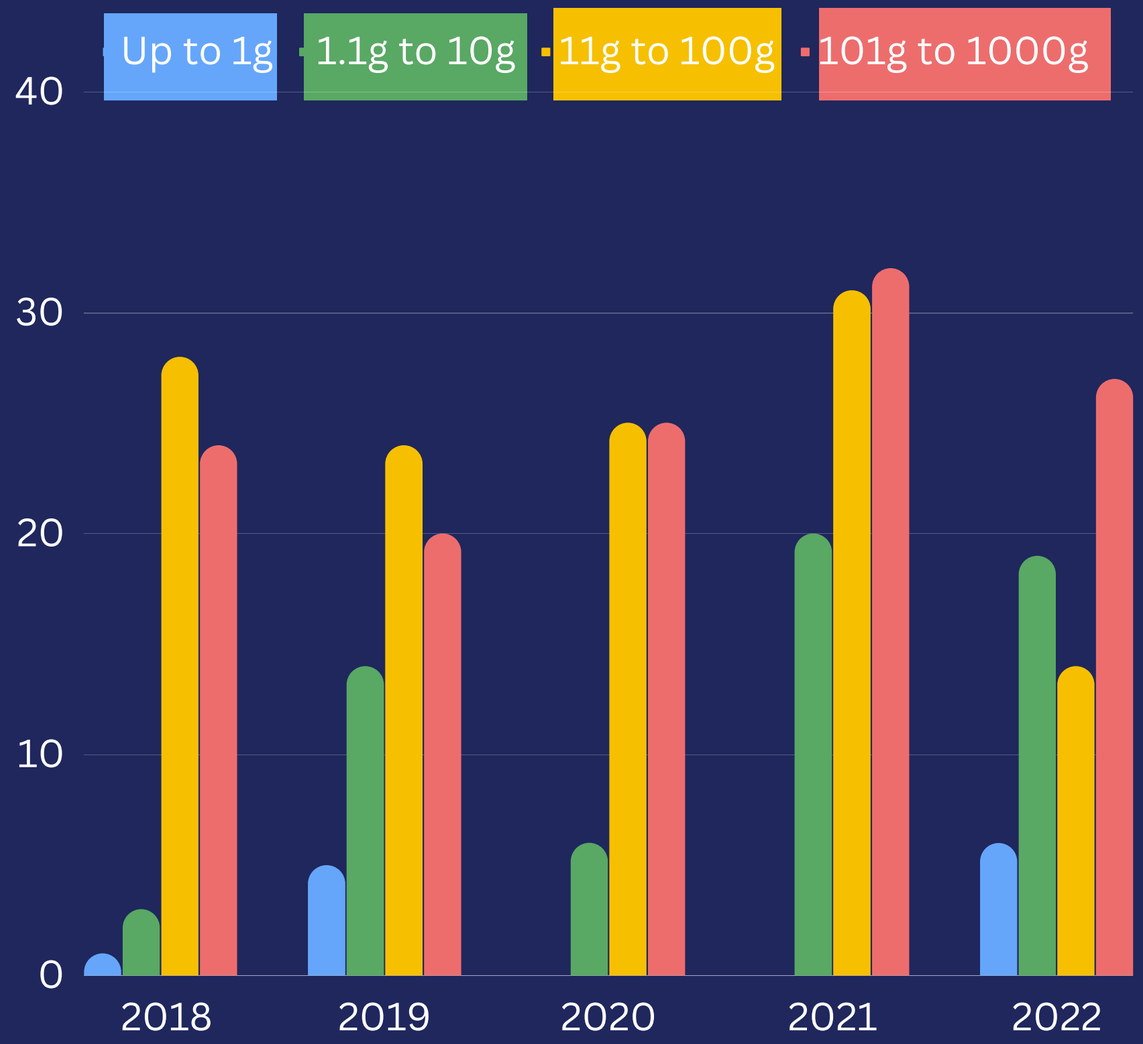
Bulk Project Summary 2018 - 2022



R&D Performance Metrics 2018 - 2022



Performance Metrics

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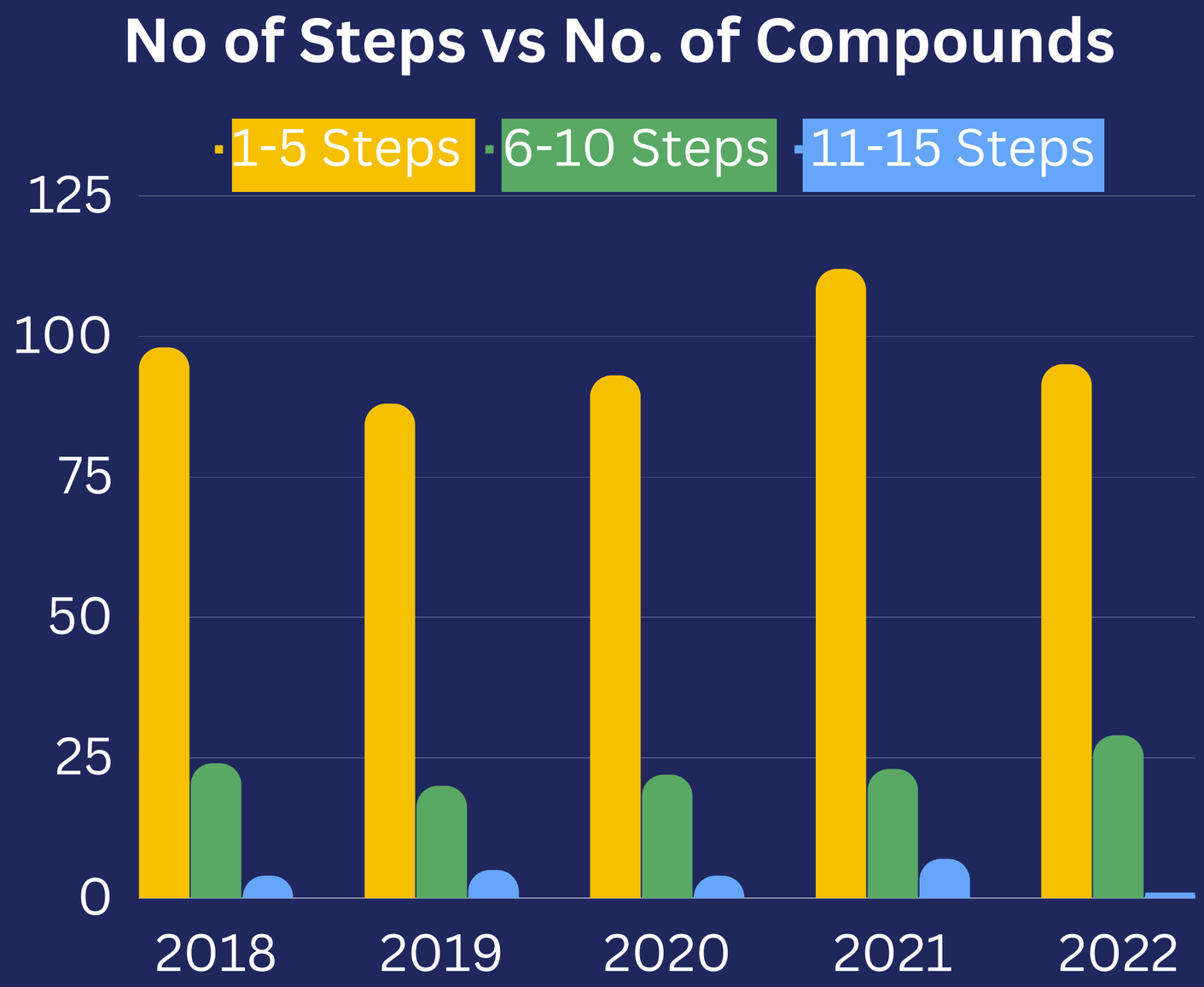

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ISO Certifications

ISO 9001: 2015
Quality Management System

ISO 14001: 2015
Environmental Management System

ISO 45001: 2018
Occupational Health & Safety
Management System

Quality Management

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EH&S - Management Systems

1. Define the work
Review, Work Instructions, Daily Meetings & Weekly Meetings, Monthly Reviews

2. Identify Hazards
Job Risk Assessment, Area Risk Assessment, Process Evaluation, Work Planning

3. Develop Controls
Write Procedures, Perform Training, Issue PPE, Issue Work Permits, Engineered Controls, Admin Controls

4. Perform Work
Pre-job Briefing, Job-site Walk-Down, Wear PPE, Execute Procedures

5. Feedback & Improve
Safety Committee, Self Evaluation, QA Reviews, Feedback Meetings, Self Assessment, Inspections

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Basic GMP-like Services

- Intermediates will be synthesized under basic GMP guidelines
- Raw Materials are tested, quarantined and released for manufacturing
- Vendor qualification
- Process Validation before scale up (on Client's request)
- Provision of documentation for submissions
- Development of Analytical Methods
- Synthesis, Isolation and Characterization of Impurities
- Reference Standard Synthesis

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IP & Confidentiality

- Confidentiality, non-compete & disclosure, upfront patent assignment agreements signed with all employees
- IP ownership is assigned to the customer upfront, and all IP developed during the project execution belongs to the Client
- USB ports disabled from all employee workstations
- Use of cellphones are not permitted in the work premises and personal email access not allowed
- IT firewall and secured server
- Clients and Projects are designated with unique code system and project details are only accessible to the Principal Scientist / Senior scientists assigned
- All the project reports are encrypted

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Project Management

CiVentiChem has a strong system of Project Management to ensure the project is executed efficiently and the customer is satisfied. Our Project Managers focus on communication and provide the following services to our clients

Communication

- A single point of contact for all communication
- Regular updates and scheduled virtual meetings
- Timely communication on project goals, progress & challenges

On-Time Delivery

- A clearly defined timeline for the project including milestones
- Internal monitoring to ensure project is delivered on time

Within Budget

- The detailed proposal will reflect the customers prioritization of individual activities
- A detailed proposal outlining the costs of individual services

Customer Satisfaction

- Ensure customer satisfaction during the project through regularly scheduled status meetings
- Follow up on final reports and other deliverables

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Fee for Service (FFS)

In this business model the price and timeline will be fixed. This is best suited for Impurities, ref. standards, advanced intermediates, NCEs & APIs on Kg to MT scale

Full Time Equivalent (FTE)

This is for full time research programs to work on projects exclusively for a certain period (1-2 y) and the targets will be delivered as per client's requirement, schedule and priority. The cost of consumables and labour are billed to client

Collaborative Discovery Model

In this business model both the teams agree to certain milestones during the project execution and also the research program progress, where both the teams intellectually support each other. The project is considered complete after the final compounds are received by client for their future discovery pipeline

Contact Us

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THANK YOU

30 years of Excellence in providing Simple solutions for Complex Chemistry problems