



Bhargava

Consulting Group

**CONSULTANCY
SERVICES**



Contents

Introduction.....	3
1. Company Overview.....	4
2. Human Resource Services	5
3. Medical Device & IVD Medical Device Service.....	8
4. Contact Us	11





Bhargava Consulting Group

INTRODUCTION

Bhargava Consulting Group (formerly known as Bhargava HR Solution) was established in 2017 with a policy of "Sourcing & Placing of Top Talent" The Bhargava HR Solution explored in 2023 for the Human Resource services, and Regulatory & documentation services to the Medical Devices, IVD Medical Devices, Diagnostics Laboratories & Pharmaceuticals industries with the name of Bhargava Consulting Group (BCG). The Bhargava Consulting Group majorly covers three verticals as appended below but not limited to;

1. Human Resource Services
2. Medical Device Services
3. IVD Medical Devices Services
4. Pharmaceuticals Services
5. Diagnostics Laboratory Services



Bhargava Consulting Group

1. COMPANY OVERVIEW

Bhargava Consulting Group strives to provide our clients with the best Human Resource services, and Regulatory & documentation services to the Medical Devices, IVD Medical Devices, Diagnostics Laboratories & Pharmaceuticals industries.

1.1. Company summary:

Bhargava Consulting Group (formerly known as Bhargava HR Solution) was established in 2017 with a policy of "Sourcing & Placing of Top Talent" The Bhargava HR Solution explored in 2023 for the Human Resource services, and Regulatory & documentation services to the Medical Devices, IVD Medical Devices, Diagnostics Laboratories & Pharmaceuticals industries with the name of Bhargava Consulting Group (BCG).

1.2. Mission:

Build a mutually profitable relationship with the customers, ensuring their long-term success, through the understanding and fulfillment of their needs and the needs of their customers as well.

1.3. Company history:

The company started on 25th December 2017 as a recruitment agency. Earlier in 2018, Received our first HR Consultancy and expanded to Delhi, Uttar Pradesh, Panjab & Himachal Pradesh,

In the mid of the year 2019, Launched our first version of HR services and initiated the healthcare consultancy services of documentation & regulation.

Earlier in 2023, BCG Explored Medical Devices, IVD Medical Devices, Diagnostics Laboratories & Pharmaceutical Consultancy. Bhargava HR Solution was renamed to Bhargava Consulting Group.

1.4. Market:

Bhargava Consulting Group aims to work Pan India, Currently, BCG provides services to the Indian state as mentioned below;

- | | |
|-----------------|--------------------|
| ❖ Delhi - NCR | ❖ Himachal Pradesh |
| ❖ Uttar Pradesh | ❖ Maharashtra |
| ❖ Panjab | ❖ Tamil Nadu |



2. HUMAN RESOURCE SERVICES

Bhargava Consulting Group offers expert consultancy services to help businesses achieve their growth objectives. Our team of experienced consultants provides valuable insights and guidance to help businesses make informed decisions. We partner with businesses to help them navigate through complex challenges and achieve sustainable growth.

2.1. Recruitment Services:

BCG provides the best possible talent for your full-time hiring needs without leaving your pockets empty. We beat all the competition fees and guarantee the best talent.

INDUSTRIES WE SERVE (not limited to)

- a) Pharmaceuticals Industries
- b) Medical Devices and IVD Medical Devices industries
- c) Diagnostics Laboratories
- d) Testing Laboratories
- e) Food and Beverage industries
- f) Real State
- g) Call Center
- h) Accounting
- i) Manufacturing
- j) Maintenance Tech
- k) Warehouse & Distribution

2.2. Talent Management Solution

In today's dynamic business needs, screening becomes an important aspect of the talent acquisition and recruitment process. To get highly efficient professionals, the screening process should be properly Defined and well executed.

BCG provides highly targeted and 360-degree talent acquisition solutions. We do all kinds of staffing. this includes;



Bhargava Consulting Group

- a) Permanent staffing
- b) Temporary staffing
- c) Campus recruitment

Our Process of Talent Acquisition

We start with understanding the organization's requirements – the position, the attitude needed, the qualifications, and the kind of experience, looking for.

We create a job description that defines the requirements in detail. This step is very crucial. A proper Job description helps in attracting the right kind of resources. Hence, it acts like the first step of filtration – a very important part of talent acquisition strategies.

Once the Job description is established, the next step is to approach the right kind of databases for the talent hunt. This can prove to be very tedious as well as time-consuming work. One has to go through all available databases to approach the targeted professionals. Our talent acquisition strategy combs through all the available resources quickly and efficiently to approach the right talent.

As a part of further screening exercises, we do an extensive background check. This helps in understanding whether the candidates are fit for the organization. Then we provide the necessary training and guidance to make them the most eligible candidates for the required position.

2.3. Employee Relations Strategy and Management

Employees are the backbone of an organization. They are the most one of the important resources and the most critical to deal with as well. Hence, it takes special skill and empathy for human resource personnel to successfully channel this very important and highly powerful resource.

BCG provides both;

- a) Placement of well-experienced and efficient HR professionals for the organization,
- b) Employee relations management consultancy to fulfill HR needs.

We have a team of well-trained and experienced HR professionals who know the art and science of employee relations management. They are sourced from highly reputed HR Institutes. Each of our executives has experience in HR Processes like;

- a) Identifying employee needs;
- b) Developing employee relations strategy;



Bhargava Consulting Group

- c) Setting up of workflow management system;
- d) Establishing proper channels for open communication;
- e) Creating a transparent working environment;
- f) Measuring and monitoring productivity;
- g) Maintaining work-life balance amongst employees;
- h) Creating a social work culture;
- i) Foster human resources and employee relations;

We understand that no company can reach its maximum potential if its workforce is not motivated enough. Our employee relations management system makes work challenging and interesting for the workforce while keeping the work environment friendly and encouraging.

We provide 360-degree Human Resource Service and management solutions that are designed keeping in mind organizations

- a) Vision
- b) Mission
- c) Business goals
- d) Employee background
- e) Growth of the organization as well as employees.
- f) Employee Key Performance;

Therefore, each of our clients gets customized employee relations management.



3. MEDICAL DEVICE & IVD MEDICAL DEVICE SERVICE

The Bhargava Consulting Group is a leading provider of consulting services to the medical and healthcare industries. Our team of industry experts is dedicated to helping clients make informed decisions and create successful strategies related to medical device services. We offer a comprehensive range of services that cover every aspect of the medical device and IVD Medical Device industry, from product safety and regulatory compliance to market access and reimbursement. Our tailored approach ensures that clients receive personalized advice and support to meet their specific needs.

3.1. Plant Set Up:

The Bhargava Consulting Group has extensive experience in the medical device industry, providing a full suite of services to assist businesses in the setup and management of a medical device plant. Our in-depth knowledge and expertise enable us to provide the best advice and assistance for your business to achieve success.

Our Plant Setup service specializes in manufacturing medical devices and in-vitro diagnostic (IVD) medical device products. Our team of experts will help you obtain the necessary regulatory approvals and design a manufacturing process flow that is tailored to your unique needs. We offer comprehensive project management and technical support to ensure your project is completed on time and budget.

3.2. Product licensing:

Bhargava Consulting Group offers comprehensive medical device & IVD Medical device licensing services (CDSCO Approvals) for businesses in all stages of the development process. With a team of experienced professionals, our goal is to maximize the efficiency of the process and obtain regulatory approvals in the most timely and cost-effective manner. This includes all the services related to CDSCO;

- ❖ Test License
- ❖ Manufacturing license
- ❖ Free Sale Certificate
- ❖ Non-Conviction Certificate
- ❖ Market Standing Certificate
- ❖ Neutral Code



Bhargava Consulting Group

3.3. Regulatory Services:

Our Regulatory Affairs Services assist clients in navigating the complex and ever-changing regulatory landscape. We specialize in medical devices and IVD medical device licensing, certification, and registration, so you can be sure your product is compliant and ready to go to market. With our expertise in regulatory affairs, we can ensure your product's success in the global marketplace.

Regulations vary depending on the medical device and the market you want to enter. Our team supports you with all necessary regulatory compliance issues worldwide.

- ✓ Medical Device Registration
- ✓ Preparation and submission of regulatory applications:
 - ✓ US - FDA 510(k) submissions
 - ✓ US - FDA Pre-Submission Applications
 - ✓ Europe - Technical files - CE submission
 - ✓ Health Canada submissions
 - ✓ Israel - AMAR submissions
 - ✓ China - CFDA submissions
 - ✓ Japan - MHLW submissions
 - ✓ Korea - KFDA submissions
 - ✓ Taiwan - TFDA submissions
- ✓ Notified Body Selection
- ✓ US FDA Establishment Registration for Medical Device Companies
- ✓ Evaluation of your device and its materials for biocompatibility compliance
- ✓ Planning and Execution of Biocompatibility Studies according to (ISO 10993-1)
- ✓ Preparation of Clinical Evaluations
- ✓ Preparing risk analysis management files (ISO 14971)
- ✓ ETO/Gamma Sterilization Validation
- ✓ Shelf-Life Testing including Accelerated Aging
- ✓ Post Market Surveillance Plans & Reports



Bhargava Consulting Group

3.4. Documentation

BCG help to design, assess, and implement Quality Management Systems that comply with FDA QSR/GMP, ISO standards, European Medical Device Directives, Canadian Medical Device regulations, and other medical device authorities' requirements.

3.4.1. Quality Management System Compliance:

We make sure through administrative and procedural activities implemented in a quality system that your medical device meets the specifications and requirements.

- a) Establishment and implementation of Quality Management Systems
- b) Issuing and maintaining the Quality Manual and Quality Procedures
- c) Establish MRB, CAPA, Training, Labeling, Document Control, and Internal Audit systems
- d) Clean Rooms, Sterilization, Packaging & Transportation validations
- e) Gap Analysis - assessment of your existing compliance with the current applicable requirements

3.4.2. Auditing:

Audits are executed to determine regulatory compliance and improve the effectiveness of your processes and those of your critical subcontractors and crucial suppliers

- a) Internal Audit - Essential to continuously improve your process and essential for full regulatory compliance.
- b) Subcontractor / Supplier Audit - Audits of critical subcontractors & crucial suppliers are vital to your Quality Management System
- c) CE Pre-Audit - With a CE Pre-Audit we guide you through the audit process before the Notified Body appears
- d) Unannounced Audit by Notified Body

Bhargava Consulting Group offers on-site support during regulatory audits or regulatory inspections.



Bhargava Consulting Group

4. CONTACT US

Bhargava Consulting Group

Khasra No. 77, Old Haibatpur, Greater Noida, Uttar Pradesh 201009 (India)

Email: info@bhargavaconsultancy.com, Info@bhargavahrsolution.com

Phone: +91 9311244093,

Website: www.bhargavaconsultancy.com

Bhargava HR Solution

A-47, Agar Nagar, Prem Nagar -III

Delhi -110086 (India)

Email: info@bhargavahrsolution.com, manish@bhargavahrsolution.com

Phone: +91 9311244093, +91 9557981333

Website: www.bhargavaconsultancy.com

Bhargava MD Solution

GA-104, Pulprahladpur, PO: Badarpur,

Delhi -110044 (India)

Phone: +91 8802904502