

## Pharma Artwork Management Services

Excellence. Expertise. Efficiency.

Packaged for your success



At Vakils Premedia innovation, precision, quality, expertise and credentials of heritage come together to provide customers the signature stamp of reliability. To assure accurate, print-ready artwork for their packaging and labeling needs.

#### **WHO WE ARE**

We are a global provider of artwork and management services for Pharmaceutical and Medicinal packaging.

In a highly regulated environment, we have consistently demonstrated skills and capabilities for the transition and implementation of new business.

Our artwork and packaging services are built on a seamless, multi-layer model that converge technology, process and service to an integrated delivery of assured excellence.

At Vakils Premedia innovation, precision, quality, expertise and credentials of heritage come together to provide customers the signature stamp of reliability. To assure accurate, printready artwork for their packaging and labeling needs.

Global organizations rely on Vakils to ensure compliance, guarantee product and brand consistency, and reduce the risk of product recall.

#### **OUR SUITE OF SOLUTIONS AND SERVICES**

#### A COMPREHENSIVE END-TO-END PACKAGE OF EXCELLENCE



#### **DESIGN**

- World-class artwork studio fully integrated into our clients' workflow
- Creative solutions capture shelf space, comply with brand guidelines & regulatory requirements
- Proficient teams thorough in the latest technologies and industry trends
- → Translation & localization service



#### **PACKAGING**

- Structural design
- → Pack and mock-up creation
- 3D creation and rendering
- Braille management

# WINNING EDGE PROJECT MANAGEMENT

#### OUR SIGNATURE OF EFFICIENCY AND RELIABILITY

People, process and technology come together with reliable efficiency in our workflow management.



**Tablets** 

Manage briefs, questions and change requests.



Create technical guidelines and SOPs.



Analyze impact assessment data of proposed changes.



Ensure KPI adherence.



Interface with the site pack technologists with no loss in translation.



Comprehensive risk management covering all scenarios.

#### Result?

- ✓ Successful 'on-time' and 'first-time-right' implementation of diverse projects
- √ Thorough and well-defined implementation
- √ Consistency of excellence and reliability.

# CAPABILITIES THAT DELIVER

#### A FOUNDATION OF ASSURANCE

- Specialized and cutting edge software
   accuracy, productivity and automation
- Dedicated 'state-of-the-art' facilities
   uncompromising security and confidentiality
- Personalized client management
   accountability, ownership and consistency of quality.

#### **QUALITY**

# AN AMALGAM OF EXPERTISE, INNOVATION & CONTINUOUS IMPROVEMENT

- Strong domain experience
   in the pharmaceutical industry and packaging
- Certified to ISO / IEC 27001:2005 and OHSAS 18001:2007 standards
- Comprehensive GMP training and development
  - for all including management
- Meticulously designed SOPsfor comprehensive guidance
- → Regular customer audits
  - to ensure full standard compliance.

#### **INNOVATION**

## BINDING TECHNOLOGY, PROCESS & SERVICE

- An integrated technology system
   global, regional and local Product
   Lifecycle Management (PLM) and
   customized systems
- Hosted, secure artwork and packaging management
- Business process management integrated at regional PLM
- Remote access solution
   interface global PLM and our design center.

#### **ADVANTAGE VAKILS**

OUR ADVANTAGE, YOUR SUCCESS FACTORS

- → Product & brand consistency
- → Compliance
- → Quality
- → Zero product recall
- → Efficiencies
- → Content editing

We have long-term partnerships with brand owners and packaging design agencies to offer end-to-end design and layout services for foolproof packaging solutions.

#### **OUR HERITAGE**

#### WHERE HISTORY, PIONEERSHIP & LEADERSHIP CONVERGE

Our parent company Vakils is a pioneer in print and publishing, with innovation as a 60-year track record. Today it stands in the forefront of specialized communication and printing services in the areas of financial printing, conversion and reporting, pre-media and IT services, book publishing and commercial printing.

Vakils Premedia creates, manages and processes information through its integrated pre-media services including packaging, prepress, page composition, colour

management, data conversion, ePublishing, and cross media services, aimed at addressing enterprises' business communication needs.

We have long-term partnerships with brand owners and packaging design agencies to offer end-to-end design and layout services for foolproof packaging solutions. From ideation and pre-print, to meeting the stringent norms of international clients in more than 20 European and Asian languages, our credentials stand tall.

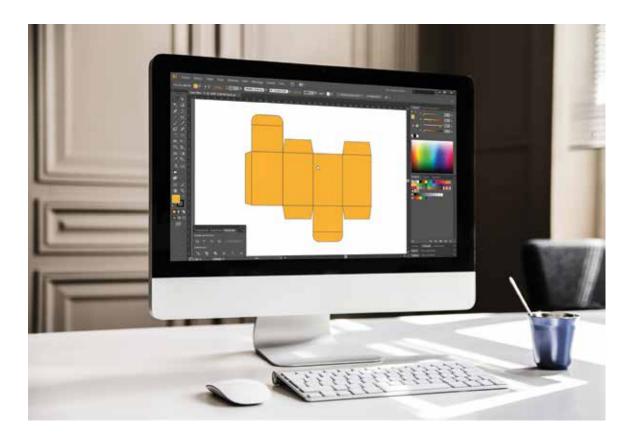
# Solutions & Services

A comprehensive end-to-end package of excellence

#### **SOLUTIONS & SERVICES**

#### A COMPREHENSIVE END-TO-END PACKAGE OF EXCELLENCE

Vakils offers a complete suite of artwork management solutions and services for the Pharmaceutical and Healthcare industries. We tailor them to help you manage your artwork and brand from the start of the creative process, right through to the final delivery of your printed product.



#### **ARTWORK PRODUCTION SERVICES**

Our end-to-end design and editorial services cover the areas of

- building specifications and drawings
- creation of artworks for new and existing packs
- translation of packaging content and
- proofreading in multiple languages

Our experienced pharma teams comprise dedicated project managers, highly trained QA professionals and re-branding management specialists. Their total understanding of specific requirements for the pharmaceutical industry ensures your complete satisfaction.

Our world class, quality driven artwork studio outsource service can integrate fully into your current workflow to provide the following services:









#### **INSERTS AND BOOKLETS**

- Cleaning up of text
   remove extra words,
   lines, spaces and colors
- Amend text flowing
   as per template
   specifications
- → Manual/digital check
- Create certified PDF
   using preflight software (Pitstop).

#### **ARTWORK**

- Execute annotations
- Paginate as per template specifications
- Create Braille, barcodes and material ID
- Incorporate process color
   PMS color or special color (special varnish, UV colors, security inks etc.)
- Create certified PDF through a preflight software (Pitstop).

#### **PROOFREADING**

- Manual proofreading with standard proofreading marks
- Digital proofreading

   using tools like text
   verification tool,
   digital-page.

Our workflow and escalation process ensures seamless coordination for efficient and accurate proofreading between the graphic designer (providing the physical file to the proofreader as hard copies of source file, certified PDF, country specific guidelines and model), the proofreader and the respective coordinators.









## REPRO & PREMEDIA SERVICES

Our Repro and Premedia services include

- Prepress preparation work to customers' specifications
- Trapping, glue codes, step and repeat, ripping,
   1-Bit TIFF delivery
- Color management programs to various standards
- Contract proofing (Digital, remote)
- Press pass services
- Print vendor auditing and ongoing control programs.

#### PACKAGING SERVICES

- → Structural design
- Pack and mock-up creation
- → 3D creation and rendering
- → Braille management

#### **CREATIVE SERVICES**

Our skilled and experienced design teams deliver creative services that you need for your market.

We are well versed with your complex challenges of premium shelf space in the global marketplace. We understand you need effective packaging to comply with brand guidelines, regional and regulatory requirements. Consider your mission accomplished.

#### **BRAND MANAGEMENT**

Vakils Premedia systems are designed to maintain your brand integrity from concept, throughout the localization and premedia workflow to delivery to your print vendor.

Our checks and controls guarantee consistent design and reproduction of your brand on a global basis. Our skilled and experienced design teams deliver creative services that you need for your market

# Quality & Standards

Always a shade better

#### **QUALITY & STANDARDS**

#### ALWAYS A SHADE BETTER

At Vakils, achieving high quality levels is an integral part of our customer relationship philosophy. Our documented quality system clearly defines our policies, processes and procedures, and ensures that we exceed standards at all levels to ensure your success.



#### ISO ACCREDITATION

The International Organization for Standardization (ISO) is the largest standards organization in the world, with a network of standards institutes from 159 countries. The ISO 27001 is a set of procedures covering all key processes within a business and ensures that these processes are efficient, effective and are monitored consistently allowing the company to continuously improve on its processes.

Vakils is certified to ISO / IEC 27001:2005.



#### **GMP STANDARDS**

GMP refers to the Good
Manufacturing Practice
Regulations promulgated
by the US Food and Drug
Administration (FDA). These
standards and regulations,
which have the force of law,
require a quality approach
to manufacturing and services,
and address issues including
record keeping, personnel
qualifications, sanitation,
cleanliness, equipment
verification, process validation,
and complaint handling.

Vakils is a GMP certified company.



#### **OHSAS STANDARDS**

BS OHSAS 18001, the framework for an occupational health and safety management system, requires policies, procedures and controls to achieve the best possible working conditions, aligned to internationally recognized best practices.

Vakils is certified to OHSAS 18001:2007.

## EXACTING PERFORMANCE PARAMETERS

Our performance criteria are designed to outperform the most stringent requirements of quality.

#### **EXTERNAL RE-RUNS**

Our target for external re-runs is zero.

#### SERVICE LEVELS

This is measured by people management, people retention and partnership agreements.

#### **DELIVERY TIMES**

Our target deliveries operate to the following demanding schedules

- < 5 business days from receipt of standard jobs
- < 2 business days from receipt of rush jobs</p>
- <1 business day for jobs during the launch period.

Target adherence to the schedule – 100%

#### MONITORING AND TRACKING

Standards of service and performance are meticulously tracked through

- Weekly Quality Reports
- Weekly Efficiency Reports
- Error Log Reports
- Delivery Reports

#### ENHANCING EFFICIENCY

All our workflows are designed with a thorough and up-to-date knowledge and understanding of all relevant legislation (MHRA, EMEA and FDA).

Our SOPs are crafted for comprehensive guidance and rules for our staff and total confidence to our clients. We deploy regular customer audits to ensure full standard compliance.

At Vakils, we deploy WebCenter, a powerful web-based packaging management platform, to manage your business process, approval cycles and digital assets.

WebCenter's versatile and powerful search capabilities, online viewing and annotation tools provides the advantage of automated document publishing for approval and review, centralized asset management and progress reporting and intuitive packaging briefing forms and workflow. This results in significant slashing of effort and turnaround times, better asset reusability and reduction in costs. All of which contribute to our outperformance.

## A CULTURE OF CONTINUOUS IMPROVEMENT

We maintain close client collaboration to accurately map production activities for process improvements, eliminate errors and drive continual growth.

Internally, we continually improve our R&D process to ensure that we remain at the forefront of our industry.

# Technology & Infrastructure

A Guarantee of Dependability

#### **TECHNOLOGY & INFRASTRUCTURE**

A GUARANTEE OF DEPENDABILITY

Innovation is a constant Mantra at Vakils.

Our artwork management services are built on a multi-layer model that efficiently integrate technologies, processes and services to create and deliver operational excellence. At Vakils, the powerful effectiveness of our process and service layers hinge and rest on a strong foundation of technology and infrastructure.



#### **TECHNOLOGY SYSTEMS**

Our integrated technology system includes global, regional and local Product Lifecycle Management (PLM) and customized systems based on process maturity.

- Hosted, secure artwork and packaging management
- Integrated PLM or hosted solutions for local PLM
- Business process management integrated at regional PLM
- → Remote access solution to interface global PLM and our design center.



We deploy the most effective and up-to-date software and technology tools to ensure the best results for our clients.

- → Adobe Indesign inserts & booklets
- → Adobe Illustrator and EskoDeskpack – artwork
- Text Verification Tool character by character digital comparison
- Pitstop PDF preflight tool
- → Digital Page source PDF to certified PDF pixel-by-pixel comparison
- → Decoder hidden image evaluation
- → Edicode Plus material ID code check.

# Our state-of-the-art desktop and server infrastructure supports multi-hundred users for guaranteed dependability.

## STATE-OF-THE-ART INFRASTRUCTURE

Our state-of-the-art desktop and server infrastructure supports multi-hundred users for guaranteed dependability.

#### SERVER ENVIRONMENT

- Fault-tolerant Window Server domain
- IBM servers with Intel Xeon CPU's.
   8 Gigabits of RAM and 11 Terabytes of centralized disk storage.

#### **CRITICAL SERVICES**

Our data and domain servers, critical to operations, are designed to ensure 'Zero' down time.

#### **NETWORK ENVIRONMENT**

- → Gigabit Ethernet hardware running TCP/IP, and providing 1000 Mbp's access
- Network is connected to the internet backbone via a 20 Mbps dedicated optica fiber-leased line.

#### "ZERO RISK" TOLERANT DATA SECURITY

- At Vakils, we have put in place meticulous data security processes and procedures to eliminate risks and support your business requirements
- Highlights of our information security protocols include
- Compulsory Network Access through passwords
- Restricted web access and control
- Restricted PDA (smart phones) and wireless access
- → Servers located in a secure environment with access controls
- Meticulous Incident Response Plans and Procedures
- Deployment of firewalls, anti-virus, backup and restore and physical access controls with regular reporting.

#### **DISASTER RECOVERY & BUSINESS CONTINUITY PLANNING**

Our disaster recovery plan covers business applications and associated processes to transition smoothly in the event of a natural or human-caused disaster.

A comprehensive and continuous assessment of our mission-critical business processes and associated applications is in place to ensure thoroughness in disaster recovery and business continuity preparedness, and includes:

- → Periodic reports, actions and checks
- → Internal assessments and audits
- Verification criteria and procedures
- Disaster recovery plan implementation
- → Representation of the IT network design team on the DR planning committee
- Annual review process for deployment of new solutions.



#### **RESILIENCY AND BACKUP SERVICES**

At Vakils, our data storage infrastructure is designed for 'on-the-fly' data storage resiliency and dual domain authenticity. This ensure a continuously available internal network authentication and storage to avoid user network downtimes.

### BUSINESS CONTINUITY PLAN TO COMBAT NATURAL DISASTERS

Our business continuity planning is well equipped to over come the catastrophic failures or 'Level 4' failures, as they are termed.

Should a Level 4 failure occur, should the regular place of business be impacted, our critical staff will be relocated to a secure premises owned by our parent company.

Our skilled and trained Emergency Response Team (ERT) closely tracks, monitors and escalates the priority of any disaster for quick and immediate corrective actions. For instance, a massive failure of the primary data servers would constitute switching to an alternative processing site, or purchasing and installing new servers, very quickly.

#### **EMERGENCY RESPONSE MANAGEMENT**

Skilled and trained ERT and Area Recovery Management Teams (ARMT) are equipped to handle management of failures.

Functional ARM Teams take care of the following:

- Damage assessment and salvage
- Transportation
- → Public information
- → Personnel
- Technology
- Communications
- Safety and security
- Restoration

#### CRISIS MANAGEMENT CENTER

The central Crisis Management Center (CMC) is embedded in the contingency plan to coordinate activities and direct the recovery process.

Should the primary place of business not be accessible, the safety and security coordinator will establish a CMC as close as possible to the primary place of business, from where voice and data communications will be established.

# Capabilities

Stretching for sustained excellence

#### **CAPABILITIES**

#### STRETCHING FOR SUSTAINED EXCELLENCE

Sustained excellence has been Vakils' vision, mission and raison d'etre at all times. The success of the 8-year young Vakils Premedia is founded on the strong credentials of its 60+ year parent company, who have been pioneers in every development in the media, publishing and communications industry.

- Over 150,000 artworks created to date for the pharmaceutical industry
- Multi-language capabilities
- Deployment of cutting edge technologies and systems for design, operations and delivery – software, hardware and infrastructure
- Dedicated teams for client management and coordination – clear accountability, fully trained, competent and robust talent pooll, impeccable customer relationship management
- Operational excellence delivered through a multi-layer model for efficient integration of technologies, processes and workflow management

- Expert knowledge and thorough understanding of all relevant legislations and requirements (MHRA, EMEA and FDA). Additional capabilities in regulatory compliance for labeling and serialization
- Certified for ISO/IEC 27001:2005 and OHSAS 18001:2007 standards; comprehensive GMP training and development program for entire staff
- Meticulous SOPs for all production processes
- Robust IT systems and data security standards. Dedicated facilities for data security and confidentiality
- Robust and fail-proof disaster recovery and business continuity programs and protocols.

It is this strength and advantage we offer our clients to help them tackle their multi-faceted challenges – consistency of quality, scalability, cost pressures, adherence to diverse and demanding standards and regulatory compliance, data security, workflow integration between multiple stakeholders, deadline pressures.







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