MDCCD 2022-2025 STRATEGIC PLAN

WHO WE ARE

MDCCD MANAGES AND DELIVERS NATIONAL COMPLIANCE AND ENFORCEMENT PROGRAMS FOR MEDICAL DEVICES; BLOOD; DONOR SPERM AND OVA; CELLS, TISSUES AND ORGANS; CLINICAL TRIALS; AS WELL AS MONITORING AND ENFORCING THE IMPORT REQUIREMENTS RELATED TO HEALTH PRODUCTS AT THE BORDER.

VISION

TO BE A WORLD-CLASS COMPLIANCE AND ENFORCEMENT ORGANIZATION WITH LEADING-EDGE PRACTICES WHICH PRODUCE VISIBLE, MEASURABLE AND POSITIVE RESULTS TO PROTECT CANADIANS, THROUGH AN ENGAGED AND HEALTHY WORKFORCE.

MISSION

TO BE A COMPLIANCE AND ENFORCEMENT LEADER THAT INFORMS AND PROTECTS CANADIANS FROM THE HEALTH RISKS ASSOCIATED WITH VARIOUS HEALTH PRODUCTS AND REGULATED BIOLOGICAL MATERIALS.

STRATEGIC OBJECTIVES

TRANSFORMATION

Transform and improve our C&E approach to become more agile, consistent and risk based

MODERNIZATION

Establish an efficient and responsive approach to program delivery

PEOPLE AND WORKPLACE

Create and support a respectful, resilient and thriving workplace

GUIDING PRINCIPLES

- ROEB TRANSFORMATION ROADMAP
- CHANGE MANAGEMENT PRINCIPLES
- ROEB WELLNESS CHARTER

PILLARS

TRANSFORMATION

TRANSFORM AND IMPROVE OUR C&E APPROACH TO BECOME MORE AGILE, CONSISTENT AND RISK BASED

OBJECTIVES

Objective 1: Maximise operational efficiency through the strategic use of resources, partnerships, and process automation and optimization

Objective 2: Implement data analytics, enhanced risk-based activities and intelligence gathering to inform operational and strategic decisions

Objective 3: Enhance program and regulatory agility to better respond to emerging global and domestic issues

PRIORITIES

Objective 1:

- PPAD - Adapt and leverage automation of licensing activities, reporting functions, directorate organizational charts and other administrative activities
- MDCP and CCBO - Create and/or continue the implementation of the Transformation Roadmaps
- MDCP and CCBO - Implement hybrid inspections where viable
- MDCP and CCBO - Design an efficient and effective process for responding to inquiries for Border Operations and MDCP including general process improvements and the use of e-solutions (e.g. Virtual assistant and/or automation of responses)
- CCBO - Transform how BPCP delivers its core mandate by exploring suitability of conducting alternate compliance and enforcement activities to maintain oversight
- CCBO - Continue to implement oversight for sponsor/CRO for CTCP
- MDCP - Continue to modernize the Manufacturer's Certificate to Export process (e.g. exploring automation and cost recovery)
- MDCP - Enhance C&E approaches for non-compliant MDEL holders

Objective 2:

- PPAD - Implement and update C&E tools (e.g. robust Site Risk Profiles)
- PPAD - Ensure continued data analytics capacity
- PPAD and CCBO - Explore the use of a "focused referral model" to address the constant backlog of referrals for Border Operations
- PPAD and MDCP - Continue development of the risk intelligence tool, CONSILIUM, for Class II-IV manufacturers to strengthen post-market oversight

Objective 3:

- PPAD - Contribute leadership and C&E perspective to the development of the Advanced Therapeutic Products (ATP) regulatory pathway
- PPAD and MDCP - Support MDEL and Recall Amendments development and implementation (Phases 1 and 2)
- PPAD and CCBO - Plan and implement the C&E components of Clinical Trial Modernization
- CCBO - Transform BPCP's compliance promotion by proactively developing and sharing online key material for industry
- MDCP - Scope and further develop medical device shortages and exceptional importation program
- MDCP - Develop and implement C&E strategy for mandatory incident reporting by hospitals
- MDCP - Develop and implement C&E strategy for private label holders

MODERNIZATION

ESTABLISH AN EFFICIENT AND RESPONSIVE APPROACH TO PROGRAM DELIVERY

Objective 1: Centralise key horizontal activities to better support programs

Objective 2: Improve operational processes to be more effective and efficient

Objective 3: Improve IT systems to facilitate program end user experience

Objective 4: Engage and share risk intelligence with domestic and international regulatory partners and stakeholders

Objective 1:

- PPAD - Develop and implement a data and information management plan and strategy to securely store and access directorate information and data
- PPAD - Develop and implement a centralised QMS function and dashboard by leading a data integration project to improve and streamline quality management
- PPAD - Lead and promote quality management principles to support continuous process and program improvement
- PPAD - Support PRSD in the development and implementation of the ROEB FDA designation Directive and the certification standard
- PPAD - Support the Directorate in the integration of the new Office 365 tools and SharePoint into daily operations and activities

Objective 2:

- MDCP and CCBO - Examine and strengthen risk-based approach to inspections
- CCBO - Determine the viability of centralizing the mailing of admissibility determination letters for Border Operations
- CCBO - Develop program specific training modules for BPCP, CTCP and Border Operations
- MDCP - Strengthen workload management of compliance verification incident reports

Objective 3:

- PPAD - Support IT system development to replace existing databases (e.g. Inspection Reporting System (IRS) and eCES) and explore development of new databases (e.g. IP-628)
- PPAD - Develop interim IT solutions for Biological Products database (e.g. IRS)
- PPAD - Leverage the community practice to ensure access to new technology and IT (e.g. Power BI, Tableau, ROEB Data Lake, Tensor Flow, RPAs, etc.)
- CCBO - Collaborate with HPCD and IMSD to update and further develop the Border Centres Operational Database (BCOD)
- MDCP - Develop and implement an IT strategy for MDCP by confirming business and data requirements and optimizing MDCP's use of technology and IT tools

Objective 4:

- PPAD and CCBO - Enhance international partnerships with key regulators (eg. USFDA, MHRA, WHO)
- CCBO - Increase transparency and information sharing of compliance and enforcement activities for CTCP with stakeholders and the public
- CCBO - Proactively engage the CBSA operational senior management on emerging issues at the border and workload management
- CCBO - Strengthen collaboration with HPFB partners
- MDCP - Strengthen collaboration with Health Canada's medical devices partners (MDD, MHPD)
- MDCP - Regular information exchange with industry associations (e.g. Medtech, DIAC)
- MDCP - Establish regulatory engagement with US FDA Office of Regulatory Affairs

PILLARS

PEOPLE AND THE WORKPLACE

CREATE AND SUPPORT A RESPECTFUL, RESILIENT AND THRIVING WORKPLACE

OBJECTIVES

Objective 1: Continue to support employee's mental health and wellness

Objective 2: Foster an environment where employees are engaged and are provided with open, clear and transparent communication

Objective 3: Support a bilingual work environment where staff can work in the language of their choice.

Objective 4: Support employee career development and progress by providing fair, open and transparent opportunities and recognising and celebrating achievements

Objective 5: Provide timely access to mandatory training

PRIORITIES

Objective 1:

- DGO/Shared Priorities - Review and implement the recommendations of the MDCCD Workplace Wellness Committee, as appropriate
- DGO/Shared Priorities - Support the implementation of the ROEB Workplace Wellness Charter
- DGO/Shared Priorities - Integrate SGBA+ and support diversity and inclusion
- DGO/Shared Priorities - Support employee re-entry in the workplace and ensure optimum communication and collaboration between virtual and in-person staff

Objective 2:

- DGO - Promote regular, meaningful interactions between senior management and employees
- DGO - Issue the MDCCD Quarterly Newsletter to inform staff about developments, successes and employee movement
- MDCP and CCBO - Build virtual team cohesion by providing networking and collaboration opportunities (e.g. team meetings)

Objective 3:

- DGO/Shared Priorities - Ensure incumbents (managers and supervisors) meet positional language requirements
- DGO/Shared Priorities - Integrate language training considerations into succession planning
- DGO/Shared Priorities - Provide part-time or full-time language training opportunities for career development

Objective 4:

- DGO/Shared Priorities - Focus on employee career development and retention
- DGO/Shared Priorities - Maintain succession plan for key positions
- DGO/Shared Priorities - Routinely recognize employee contributions, accomplishments and successes

Objective 5:

- DGO/Shared Priorities - Provide financial support for employee training and development where required
- DGO/Shared Priorities - Identify and communicate all corporate mandatory training requirements to support employees' compliance and continuous learning (e.g. workplace violence & harassment training)
- PPAD - Create an onboarding package for managers and employees