**HEALTH CANADA**

**Health Product and Food Branch**

**Project Charter – Under $250,000**

**Screening and Review Tool (SRT)**

**Enhancements**

**U1801-SRT**

**Version: 3.1**

**February 2, 2018**



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# Section 1 - Charter Introduction

## 1.1 Document change control

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision Number** | **date** | **Description** | **Author** |
| 0.1 | July 14, 2015 | Initial draft of charter | M. Houle |
| 1.0 | August 6, 2015 | Approved | M. Houle |
| 2.0 | September 16, 2016 | Revised version after project extension | M. Houle |
| 3.0 | January 9, 2018 | Revised version after project expansion | M.Houle |
| 3.1 | February 2, 2018 | Revised version input from RMOD and IMSD | M.Houle |

## 1.2 Executive summary

The overall project aims to enhance the screening and review processes though automation. The project has established a suite of screening and review tools accessible through the Microsoft Word ribbon. The suite of tools are designed to facilitate the screening and review processes by:

* autopopulating tombstone information in submission screening reports, review reports, executive summaries, records of decision, correspondence (acknowledgment, screening acceptance letter, NOC, NOL, NOD), clarifaxes and information requests at the press of a button on the basis on the submission control number;
* providing a flexible interface and storage mechanism to manage, track, trend and report on submission review issues throughout the product lifespan;
* incorporating all the BGTD-related information content of the Post-NOC guidance document and assist in the identification of changes, categorization of submissions and determination of documentation requirements through user-interaction;
* providing context sensitive information in the form of national and international guidances, points-to-consider documents, template content help, and content developed in-house (lessons learned, case studies, etc… ) to support the review process; and
* providing a series user interfaces designed to allow for updating, expanding or extending the information content of the tools or the fields amenable to autopopulation.
* Providing interfaces for extracting business intelligence information from the growing database
* Providing a light project management framework for submission workload and progress management

The goal of the implementation of this suite of tools is increase review and screening efficiency and quality by reducing the need to perform repetitive tasks; by providing access to complete, up-to-date, and easily retrievable sources of information to support review and screening; and by creating a mechanism by which new information content can be developed and be made accessible to other reviewers and screeners in a simple, efficient and context sensitive fashion. These goals contribute to the following departmental priority: Priority IV - Continue to build an efficient, interconnected, and adaptable organization with improved processes, structures, and systems.

The project was initially submitted as a BGTD project in 2015 subsequent to a branch reserve funding call for proposals. The project was approved for extension of June 22, 2016 with an enhanced scope encompassing collaboration with TPD as they also had a proposed suite of tools. The tool is intended for deployment to all BGTD/TPD staff, but it is expected that the Screeners and Reviewers will make the most use of the suite of tools.

***The BGTD tool is being developed in phases whereby the different functional aspects of the tool are released sequentially. Currently, functionality for autopopulation, semi-automated screening, context sensitive reference information delivery, and flexible business intelligence reporting have already been rolled out. Enhancements to each of these tools as well as the issues management and project management modules are to be developed as part of this current project expansion.***

The estimated cost for 2017-18 with respect to the continued development and expansion of the tools from the RMOD perspective is 210K$ which includes software development and implementation costs as well as costs associated with the deployment of the tool across multiple directorates.

The key risk is delayed deployment by IMSD, as each previous rollout of the tool suite (3 so far) took 3-6 months for packaging.

## 1.3 Authorizations

|  |  |
| --- | --- |
| **Project Champion** | **Project Sponsor** |
| *Name:* Cathy Parker  *Title:* Director General  *Organization:* HPFB - BGTD    Signature Date | *Name:* Michele Belanger-Petrucci  Acting for (Vikesh Srivastava)  *Title:* Associate Director  *Organization:* HPFB - RMOD    Signature Date |
| **Project Authority** | **Business Manager BGTD** |
| *Name:* Lindsay Elmgren  *Title:* Director  *Organization:* HPFB - BGTD - CBE    Signature Date | *Name:* Will Stevens  *Title:* Chief  *Organization:* HPFB - BGTD - BPD    Signature Date |
| **Project Manager BGTD** | **Project Coordinator RMOD** |
| *Name:* Martin Houle  *Title:* Senior Biologist/Evaluator  *Organization:* HPFB – BGTD    Signature Date | *Name:* Angelo Federico  *Title:* Project Manager  *Organization:* HPFB - RMOD    Signature Date |
| **Technical Authority IMSD** |  |
| *Name:* Kevin Black  *Title:* Client Engagement Representative  *Organization:* IMSD    Signature Date |

# Section 2 - Project Overview

## 2.1 Project summary (BGTD)

### 2.1.1 Overview

The proposal consists in developing a suite of tools as an application-level add-in for Microsoft Word to facilitate screening and review. This proposal was developed in response to a business need. Indeed a considerable of time is currently devoted to repetitive tasks with little added value such as repeatedly entering tombstone information in all sorts of documents ranging from screening and review reports, executive summaries, summary basis of decisions and all manner of correspondence (acknowledgments, clarifaxes, information requests, notices, etc…). A portion of this proposal addresses this need.

Screeners are required to ascertain the submission category, and the required documentation for specific changes to chemistry and manufacturing on the basis of the “post-NOC changes guidance”. The document, although extremely well designed and comprehensive is a 150 page document, split into 3 sections, one for each of BGTD, TPD and VDD. The document is unwieldy because of its size and also the density of the information content within. Screeners currently identify the changes by running through the applicable section of the documents, selecting, copying and pasting the relevant criteria for each of the relevant changes, then manually evaluating the submission category. Then they must select, copy and paste the relevant document requirements for each change into the review document. Finally, they must remove duplicate requirements. The screening tool proposes to partially automate this task.

Reviewers and screeners are required to integrate information from a variety of disparate sources in order to make risk based recommendations regarding the acceptability of products and changes to their manufacture, indications etc… Some attempts have been made to render this information more accessible and easily retrievable but with limited success. The current proposal addresses this need by not only making these information sources more readily available but also by allowing their retrieval in a context sensitive fashion. It is expected that in addition to reducing the amount of time required to access the information, this will also foster their use on a more regular basis. This tool will be of considerable utility as a training tool for new reviewers.

Lastly, it has been recognized that the function of reviewer requires significant on the job training and that learning is based on experience. It has also been recognized that sharing of lessons learned and issues is often limited to within the confines of product line divisions. The proposed tool offers a way for reviewers to share their experience by creating issue notes, lessons learned, or case studies for incorporation into the review tool and these will become available for viewing to all users.

In order to foster the use of the tool, we have selected to include it as a an application level add-in for Microsoft Word as this application is one of the main applications used by screeners and reviewers in the performance of their daily work tasks. The tools would be accessed as any other function in Microsoft word, i.e. by clicking icons on the Microsoft Ribbon.

The tool suite will be comprised of 5 main functional groups:

1. [**Autopopulation**] Auto population of tombstone information in documents
2. [**Screening**] Searching and navigating the Post-NOC changes guidance. Interactive controls to identify and select applicable changes and criteria from the post-NOC changes guidance and the necessary logic to select the change category and the required documents to support the proposed change based on user input. Functionality to output a formatted text directly to the review or screening report listing the applicable changes, the criteria and their status (met or unmet), the submission type, and a list of required documents applicable to the submission.
3. [**Documentation Access and Management**] Searching and retrieving documents from a complete library of internal and external documents such as procedures, guidance documents, points to consider documents, content help information for CTD sections, and other content developed in-house (lessons learned, case studies, issues of note, etc…). Content can be filtered or prioritized by product line (e.g. recombinant products vs plasma derived products have different requirements and different applicable guidance) or displayed in a context sensitive manner (e.g. only information relevant to the specific CTD section currently in the selection range of the current open document). Updating and adding data content can be performed using a built-in interface.
4. [**Submission Issues Management**] The module will allow for management of issues encountered during review. Initially, issues flagged by reviewers/screeners will be stored locally (i.e. inside the docx format as XML data). Issue categorisation, flow and resolution will be saved to the SRT database. Thus allowing issues to be managed in a holistic fashion as well as allowing for tracking, trending and retrieval through the business reporting tool.
5. [**Business Reporting**] The module will allow for flexible access to information stored within the BGTD databases. This will include a wizard to help develop queries against the SRT, DPD and DSTS databases. A storage mechanism will be developed for the queries so that queries can be re-used. The reports will be exported to Excel or other suitable formats.
6. [**Project Management**] This module is to leverage the information already captured via the screening tool to establish a light project management template, which can be updated, tracked and consulted throughout submission review.
7. [**OSE Management**] This module will incorporate specific forms which are currently being developed to support the BGTD OSE process. All data regarding the assessment of the need for OSE, the feasibility assessment as well as the OSE executing, reporting and closeout will be managed through the tool.

### 2.1.2 Detailed description of requirements and functionality

**The auto population tool:**

* Requirements
  + Connection to a reliable base data source for tombstone information
  + Connection to a local secure database to store tombstone information after initial retrieval and any other information which we need to propagate after creation (e.g. review summary), and to store active controlled content field titles and their associated connection information to the source data information (e.g. DSTS connection string, field name, etc…)
  + A Word document with controlled content fields with names that match those configured in the local database.
* Functions:
  + Auto populate
    - The application-level add-in will establish a secure connection to a local database.
    - Obtain a list of content controlled field names and the data sources.
    - Scan the document for content controlled fields with these names.
    - For those fields found, initiate a connection to the relevant data source(s) and retrieve data for the relevant control number.
    - Populate the fields from the retrieved data.
  + Save
    - Scan the document for content controlled fields with names matching those in the local database.
    - Save updated or new data to the local database (e.g. non-tombstone data)
  + Add, remove, edit auto populated field(s)
    - A user with administrative privileges will be capable of modifying the underlying data through a specially designed interface.

**The Screening tool:**

* Requirements
  + Connection to a local secure database which stores the Post-NOC changes guidance document information in a structured manner including links and associations between changes, criteria, submission classification and documentation requirements
  + For the Screen function, a populated control number field is required on the template.
* Functions
  + Search
    - A User form or custom task pane will allow for entering search terms and advanced searching options such as limiting scope of search to changes, criteria, classification, or documentation requirements.
    - The add-in will execute a query on the database on the basis of the search terms and display the associated changes, criteria or requirements depending on selection
  + Navigate
    - A User form or custom task pane will display the post-NOC changes guidance information in a tree view display with the possibility of filtering based on terms (e.g. DP, DS, controls, etc…).
  + Screen
    - After pressing the “screen” button, the user will be directed through a set of user interactions whereby one will search and/or select applicable changes and select the criteria which were met for these changes.
    - A formatted text block will then be inserted into the document at the selection point which will include the list of changes, the list of criteria for each change, which were met or unmet, the list of required documents (with duplicates removed) and the submission type.
  + Update Post-NOC Changes Data (upon revision of the guidance)
    - A user with administrative privileges will be capable of modifying the underlying data through an interface which reproduces the format used in the Post-NOC changes guidance.

**The Review tool:**

* Requirements
  + Connection to a local secure database which stores the documents, the information content, the linkages, the context tags, etc…
  + There are no special requirements with respect to the open word document to search through or navigate the content, furthermore some basic filter options will be also available (product line, DS vs. DP, etc…)
  + For content to be displayed in a context sensitive fashion, the word document must contain bookmarks or headers named according to the CTD nomenclature.
* Functions
  + Search
    - A User form or custom task pane will allow for entering search terms and advanced searching option such as limiting scope of search based on filter options
    - The add-in will execute a query on the database on the basis of the search terms and display a list of relevant search results. Clicking on a listed item will open the document either in its parent application (e.g. PDF reader) or in a user form if it is simple text.
  + Navigate
    - A User form or custom task pane will display the list of documents in a tree view display with the possibility of filtering based on terms (e.g. ICH, FDA, HC, in-house). Clicking on a listed item will open the document either in its parent application (e.g. PDF reader) or in a user form if it is simple text.
  + Context Sensitive Display
    - With the context sensitive display custom task pane open, information content will be restricted or prioritized based on a selected product line and based on the location of the cursor in the document. The add-in will identify relevant content by matching it to the first bookmark or heading up from the cursor (e.g. if the previous heading is 3.2.P.8, the list of documents and content help related to stability will be displayed).
    - Clicking on a listed document will open it.
  + Apply Bookmarks
    - Given that the context sensitive display is dependent on bookmarks, a function will be available to scan the document and apply bookmarks to lines of text which have the hallmarks of being CTD headers.
  + Submit revisions, additions, obsolescence
    - All users will have the capability of contributing to the content of the review tool by authoring changes and/or additions through an intuitive interface which will capture the changes/additions as well as structure data (e.g. tags) to allow for effective searching and context sensitive display of the documents and/or information. Contributed changes will be specially identified until vetted and approved by an administrative user
  + Approve revisions, additions, obsolescence
    - A user with administrative privileges will be capable or approving contributed additions or changes.

**Issues Management:**

* Requirements
  + A word document template with a populated control number field is required.
  + For committing issues to the database, a connection to a local secure database to store the Issue information and subsequent resolution and flow
* Functions
  + Create Issue
    - A User form or custom task pane will allow for flagging issues and associating them with a particular control number, user and function (screen, 1rst review clinical/C&M, 2nd review clinical/C&M, executive review clinical/C&M, post-NOC/NOL, or OSE). The issue will be also associated to a specific location in review document via a location tag. The issues will be stored locally in the XML data of the document until committed to the database by the user. Issues will be tagged with additional meta data such as: relevant CTD section, collection of tag words, issue type and category, thus enabling subsequent business intelligence reporting.
  + Issue Resolution Flow
    - Interfaces will allow users to resolve issues locally (never committed to database), track resolution through information requests to the sponsors, or external expertise to a final decision on issue outcome. Issues can be completely closed or remain open as commitments which can then be tracked through the business intelligence reporting tools.
  + Clarifax generation
    - At the users request, all issues marked with readied information requests will be scanned to generate an information request list in the database which will then be available for retrieval through a template for review and approval by a manager and subsequent issuance by the regulatory affairs group.

**Business Intelligence Reporting:**

* Requirements
  + A secure connection to the SRT, DSTS and DPD databases
* Functions
  + Create Queries
    - Queries joining data from the DSTS, DPD and SRT database will be create through a wizard type interface
  + Manage Queries
    - Developed queries can be stored, retrieved, copied and modified
  + Execute Queries
    - Queries can be executed and the data exported to Excel or another suitable format.

**Project Management:**

* On the basis of data captured by the screening assessment tool, a submission specific project management template will be elaborated. Users will be able to then record progress against each of the defined project elements. In addition, users will be capable to add, modify or remove project management elements to customize the template. The project management tool will propose standard timeframes for elements but will allow users to adjust the estimates. Managers will be capable of accessing the project progress for each submission with a template.
  + Functions
    - Create customized submission project management template based on Screening assessment for NCs, SNDS
    - Create standard project management templates for NDS and CTAs
    - Adjust templates
    - Record progress against templates
    - View aggregated submission progress (manager function)
    - Provide adjustable time estimates

**OSE Management (early development)**

* Provide interfaces to record evaluation of OSE need, OSE feasibility assessment, and OSE execution including the recording of OSE observations. Provide interfaces for reporting on all aspects.
* *Note: For this development period, only URS and early alpha development are to be performed.*

**Data Integrity and Safety Measures:**

* Limit capability to modify some fields (auto population tool) to categories of users.
* Access restrictions to the database will be controlled by user names and passwords. All the requirements of IT Security document (RDIMS# 206846) are met. Administrators will be able to login directly into the software in order to provide support directly at a user’s computer.
* Ability to report bugs directly through the add-in.

**Performance measurement:**

* Requirements
  + Counter for fields autopopulated, reference documents accessed, semi-automated screenings, content generated and accessed, and Issues tracked.

## 2.2 Project goals, business outcomes, and objectives

| **No.** | **Goals** | **Objectives** | **Business Outcomes** |
| --- | --- | --- | --- |
| 1 | Reduce or eliminate repetitive tombstone data entry | **A modern workplace that makes smart use of new technologies to improve networking, access to data and customer service.** We will pursue affordable, **interoperable tools and systems, and emphasize a tech-savvy and responsive culture** that puts citizens first, making investments that are appropriate to sound public finances and the concrete needs of Canadians.[[1]](#footnote-1) | Rollout of enhanced auto population tool |
| 2 | Partially automate the screening process | Rollout of the enhanced screening tool |
| 3 | Facilitate access to supporting information required for screening and review | Rollout of the enhanced review tool |
| 4 | Provide an efficient and accessible means for the development, storage, retrieval and sharing of information content to support submission screening and review | **A capable, confident and high-performing workforce that embraces new ways of working and mobilizing the diversity of talent to serve the country’s evolving needs.** We will stress the importance of competent, engaged and productive leaders, managers and employees. We will also focus on **the value of knowledge as well as learning from the collective experience in developing evidence-based options for decision-makers**.1 | Rollout issues management, business intelligence reporting tool, and project management tools |

## 2.3 Project scope

### 2.3.1 Scope definition

The project includes the following activities:

1. Development of the application level add-in for Microsoft Word with the functionalities outlined above.
2. Development of a database structure to hold the configuration data and information, the post-NOC guidance information and linkages, the resource documents and necessary linkages, and the in-house generated content.
3. Import of already available data content, information and resource documents into the database

### 2.3.2 Boundaries

|  |  |
| --- | --- |
| **Activities in Scope** | **Activities out of Scope** |
| * Development of the application level add-in for Microsoft Word * Development of a database to hold the content * Identifying a means to connect to a reliable data source for tombstone information * Import of already available data content, information and resource documents into the database * Development of new content * Development of templates for use with the suite * User training |  |

## 2.4 Milestones

### 2.4.1 BGTD

|  |  |  |
| --- | --- | --- |
| Project Milestones | Description | Expected Date |
| Project Charter | Signing of Project Charter v2.0 | 2016-09-30 |
| Phase 1 Rollout | Suite including:   * autopopulation tool add-in final release * Screening tool add-in beta release * documentation access tool add-in beta release | 2016-10-15 |
| Phase 2 Rollout | Suite including:   * Screening tool add-in final release * documentation access tool add-in final release * Business reporting beta | 2017-01-15 |
| Phase 3 Rollout | Suite including:   * autopopulation tool add-in * Screening tool add-in * documentation access tool add-in * Business reporting tool | 2017-07-30 (sent for packaging)  2017-11-28 (published by IMSD to production environment) |
| Phase 4 Rollout | Suite including:   * Enhanced autopopulation tool add-in * Enhanced Screening tool add-in * Enhanced documentation access tool add-in * Enhanced Business reporting tool * Issues Management Tool Beta * Project Management Tool Beta | Target 2018-03-31 (send for packaging) |

## 2.5 Deliverables

Status as of January 1, 2018:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Module Name | URS | Software Development | Testing | Status |
| Auto-population | 100% | 100% | 100% | Fully Deployed |
| Screening  Navigation  Automated Screening | 100%  90% | 100%  80% | 80%  50% | Fully deployed  Partially deployed |
| Enhanced Review tool | 100% | 100% | 80% | Fully deployed |
| Issues Management | 85% | 90% | 30% | ***In development*** |
| Business Reporting | 90% | 90% | 50% | Partially deployed |
| Early modules feature enhancements | 90% | 90% | 20% | ***In development*** |
| Project Management | 0% | 0% | 0% | ***In development*** |
| OSE Management | 25% | 10% | 0% | ***In development*** |

*Project deliverables:*

|  |  |  |
| --- | --- | --- |
| **Module Name** | **Task** | **Target Date** |
| Enhanced Review tool | Finalize Testing | January 31, 2018 |
| Finalize Release Software development | February 28, 2018 |
| Business Reporting | Finalize Testing | February 28, 2018 |
| Finalize Release Software development | March 31, 2018 |
| Early modules feature enhancements | Finalize URS | January 31, 2018 |
| Finalize Release Software development | February 28, 2018 |
| Issues Management | Finalize URS | January 31, 2018 |
| Finalize Beta Software development | March 15, 2018 |
| Finalize Testing | March 31, 2018 |
| Project Management | Finalize URS | February 28, 2018 |
| Finalize Beta Software development | March 31, 2018 |
| OSE Management | Finalize URS | March 31, 2018 |

*Requirements for IMSD:*

|  |  |
| --- | --- |
| **Task** | **Target Date** |
| BugFix Rollout | February 15, 2018 |
| Full Rollout | March 31, 2018 |

BGTD will be providing IMSD with the Y: drive address of a folder containing:

* A standard install package (setup.exe + .msi file)
* A configuration file
* A pre-established account (username/password)
* The instruction set we provide to users to support initial configuration

## 2.6 Project cost estimate and sources of funding

### 2.6.1 Project cost estimate

For the BGTD managed portion of the project, the cost estimate is 210000$ for the entire year. Seventy-five percent of the funds have already been spent as the project has been ongoing since the beginning of fiscal and was being cash managed by RMOD. The funds were and are to be used for a task authorization at 800$/day (approximately 200 days) and to maintain computer systems to be used for the software development and testing. In addition to the human resources already committee to this project, BGTD will also be spending 15800$ this fiscal to hire students for the purpose of furthering this project.

### 2.6.2 Sources of funding

The main source of funding is a Branch reserve fund, but some of the funds are from BGTD (15800$ for COOP student hiring). In addition, BGTD is providing a significant human resources commitment to this project.

## 2.7 Dependencies

|  |  |  |
| --- | --- | --- |
| **Dependency description** | **Critical Date** | **Contact** |
| Deployment of MS Word application level add-in to users via IMSD/SSC | Multiple | Kevin Black |

All other dependencies were resolved during the previous year.

## 2.8 Project risks, assumptions, and constraints

### 2.8.1 Risks

No technological or infrastructure related risks remain after the first year of this project. All remaining risks are related to human resource availability

|  |  |  |  |
| --- | --- | --- | --- |
| **Dependency description** | **Probability (H/M/L)** | **Impact (H/M/L)** | **Mitigation** |
| Delays in development and implementation due to low availability of business transformation analyst and/or in-house subject matter experts | M | H | Hiring of a student as an additional resource |
| Unplanned significant changes to network connectivity infrastructure | L | M | RMOD engagement with IMSD/SSC |

### 2.8.2 Assumptions

N/A

### 2.8.3 Constraints

|  |  |  |
| --- | --- | --- |
| **No.** | **Category** | **Constraints** |
| 1 | Budget | Must respect budget |
| 2 | Scope | Project is to be rolled out using a staged approach with a pilot phase conducted in BGTD for each phase. Rollout requires training to be conducted for each phase. |

# Section 3 - Project Organization

## 3.1 Project governance

The governance of this project is described in the HPFB Project Management Framework for IM/IT Enabled Projects. The governance structure has been modified to accommodate the fact that this project is not an HPFB Investment Plan project and there are no requirements to report to the Departmental Project Management Office (DPMO) or the DG IP Governance Committee. The project will be managed at the Branch level under the BEC Sub-Committee structure.

The status of this project will be tracked using HC's Project Management Framework Dashboards.

## 3.2 Project team structure

| **Project Role** | **Responsibilities** |
| --- | --- |
| HPFB PPMO | The PPMO ensures alignment with HPFB business objectives and Treasury Board Policy on Management of Projects, monitors and reports progress. The PPMO also ensures coordination between the BGTD and TPD screener/reviewer tools projects to ensure that there is no overlap and no duplication of effort. |
| Project Steering Committee | The Project Steering Committee sets project scope and objectives, provides project oversight, ensuring alignment with HPFB business objectives and business outcomes. |
| Project Management Office | Responsible for the detailed management of the project, achieving the project as scoped and planned, reporting, managing risk, completion of project documentation and managing project resources. This includes both business and technical management. |
| Subject Matter Expert Working Group | Verification and validation of business and technical requirements. Coordination of stakeholders. |
| Desktop Engineering IMSD | Packaging, QA of installation process and promotion to production environment or the application Msi file. |

## 3.3 Roles and responsibilities

|  |  |  |
| --- | --- | --- |
| **Project Role** | **Responsibilities** | **Assigned to** |
| Champion | * Provide Leadership on culture and values * Keep project aligned with the organization’s strategy and portfolio decisions. | Cathy Parker  Director General, HPFB-BGTD |
| Project Authority | * Own the business case * Focus on realization of benefits * Provide resources | Lindsay Elmgren  Director, HPFB-BGTD-CBE |
| Project Sponsor | * Govern Project Risks * Manages acquisition of technical resources * Focus on Realization of outcomes * Recommend opportunities to optimize Cost/benefit * Manages engagement between technical services, IMSD and HPFB * Coordinates TPD and BGTD tools projects to ensure there is no overlap or duplication of efforts | Michele Belanger-Petrucci,  A/Associate Director , Business Informatics, RMOD |
| Business Manager BGTD | * Coordination with RMOD * Communicate business issues and risks * Manages BGTD Resources * Directs SME engagement and communications | Will Stevens  Chief, HPFB-BGTD-BPD |
| Business Project Manager BGTD | * Coordination between BGTD assigned technical resources and the SME Team. * Reporting on progress to Project Coordinator * Focus on defining and realizing user requirements for BGTD managed elements | Martin Houle  Sr. Biologist/Evaluator,  HPFB-BGTD-BPD |
| Technical Project Manager | * Focus on providing technical environment for success. * Official contact for the Desktop Engineering team at IMSD for purposes of facilitating and negotiating the packaging process. * Resolving packaging delays and issues * Resource for packaging process procedures | Kevin Black  Client Engagement  IMSD |
| SME Team | * Develop and maintain user requirement specifications (URS). * Guide interface design choices. * Decide when specific elements of the URS have been achieved. | Sharon Allard (GRP Rep.)  Martin Houle (Project Manager BGTD)  Martin Nemec (C&M Review Rep.)  Vincent Panetta (ORA Rep.)  Laurent Cocea (Clinical Review Rep.)  Will Stevens (Business Manager)  Omar Tounetki (C&M Review Rep.) |
| Project Coordinator | * Coordinates interactions between IMSD and BGTD Project team. * Coordination between RMOD and the Technical Resource * Reporting on finances * Relays project progress and status to BEC-TIFF | Federico Angelo,  Project Manager, RMOD |

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## 3.4 Project facilities and resources

* Business transformation specialist with knowledge and experience in the field of visual basic.net programming and office application level add-in development.
* Business transformation specialist with knowledge and experience in the field of database programming and configuration.
* Subject matter experts in the fields of biologics submissions screening and review.
* COOP Students to provide support in software development, testing and project management.
* VMWare configured computers for the purpose of application level add-in development and testing (4 for BGTD).

# Section 4 - Project References

More information concerning this project can be found in the following documents:

* Branch Reserve Funding Request entitled: “U250K Proposal Template FINAL(BGTD SRT 2107).xlsx”.

# Section 5: Glossary and Acronyms

Term or Acronym Definition

SRT Screening and Review Tools

HPFB Health Product and Food Branch

RMOD Resource Management and Operations Division

SME Subject Matter Experts

TR Technical Resource

1. Blueprint 2020 - [A Vision for Canada’s Federal Public Service](http://www.clerk.gc.ca/eng/feature.asp?pageId=349#VI) [↑](#footnote-ref-1)