



Australian Government
Department of Health
Therapeutic Goods Administration

TGA Business Services (previously eBS) Drafter / Submitter roles



TGA Health Safety
Regulation

Our clients. Our focus.

TGA Business Services – drafter and submitter overview

- Overview
- Client's personal view
- Site design
- Drafter/Submitter specific information
- Viewing and changing your details

Overview

- In the new TGA Business Services site each user will have a personalised unique view based on the interactions they have with the TGA.
- Each view is based on the different interactions people have with the TGA. The TGA Business Services site is based on using roles –drafter, submitter, financial or administrator, or any combination of these.
- This PPT gives you an overview of your role and some of the new capabilities to manage contact details.
- For more information read the Drafters and submitters – questions and answers.

Client's personal view

Some clients will have multiple roles. This is an example of the view with all roles:

1. The news feed is customised for each role
2. View my organisation
3. Drafters / Submitters see Work in Progress
4. Financial users see Invoices
5. All users see Interaction history

Applications - Financials Documents - Your TGA -

Welcome Philip Smyth

What would you like to do today?

Pharma Co Pty Ltd (PC0987278A)

ABN: 77 569 875 963
ACN: 569 875 963
Web: http://www.pharma.au.com

News panel

Business gateway to eBusiness
© 2 May 2015
Services
In early 2015, the TGA launched the first of a series of upgrades to its existing eBusiness Services.

System accessibility and compatibility
© 12 May 2015
TGA is working to improve accessibility (including WCAG AA compliance) in future versions of the TGA eBusiness System (eBB).

View all drafts

Date	Identifier	Client reference	Information	Sponsor
21 December 2014	MH-2013-LH-8956-Z	PC0987278A	Liquid Caps blister pack 30mg	Pharma Co
13 September 2014	dv-2014-mc-00267-1	PC0987278A	Night time Liquid Caps blister pack 30mg	Pharma Co
13 August 2014	dv-2014-mc-00267-1	PC0987278A	Day time Liquid Caps blister pack 30mg	Pharma Co
04 August 2014	dv-2014-mc-00267-1	PC0987278A	Cold buster 50 caplets	Pharma Co
01 August 2014	dv-2014-mc-00267-1	PC0987278A	Cold buster with vitamins 50 caplets	Pharma Co
23 July 2014	dv-2014-mc-00267-1	PC0987278A	Cold buster with vitamins 100 caplets	Pharma Co
18 July 2014	dv-2014-mc-00267-1	PC0987278A	Head clear MAX	Pharma Co
19 June 2014	dv-2014-mc-00267-1	PC0987278A	Head clear early stage gel	Pharma Co
03 June 2014	dv-2014-mc-00267-1	PC0987278A	Nutri-cream 50mg tube	Pharma Co
26 May 2014	dv-2014-mc-00267-1	PC0987278A	Medi-past nutritional gel	Pharma Co

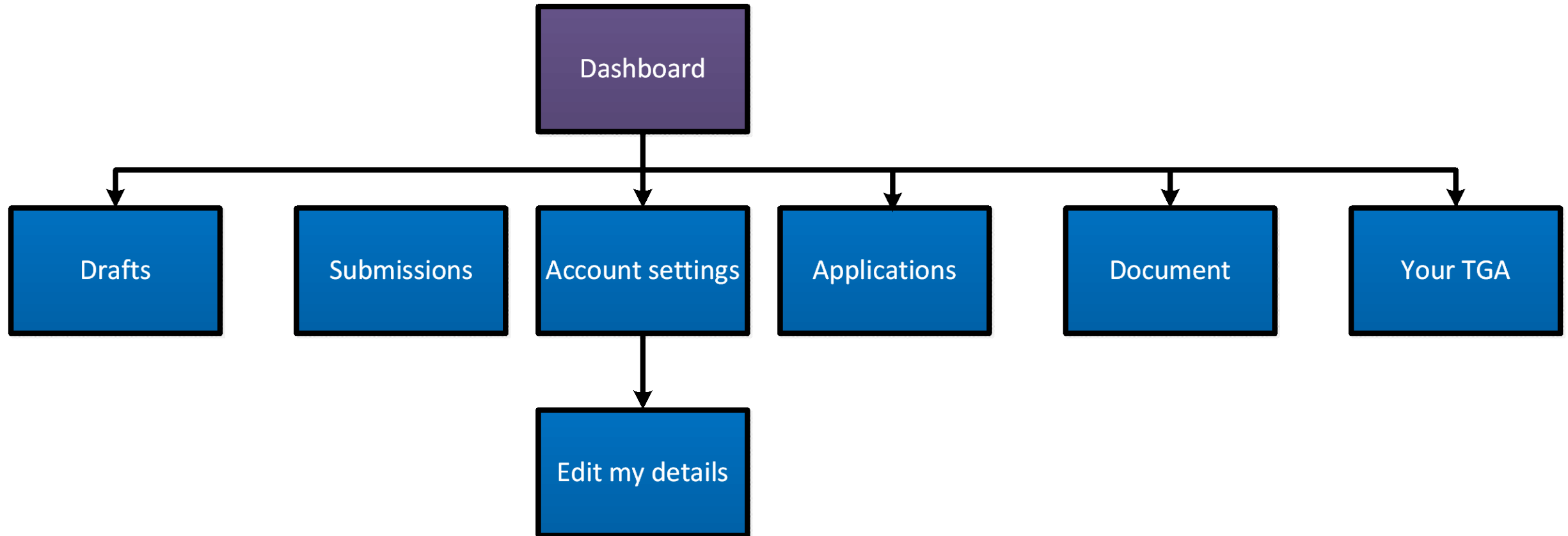
View all Invoices

Date	Invoice	Invoice amount	Actions
18 October 2014	INV001A	\$800	Actions
20 October 2014	INV088-2014	\$1010	Actions
31 October 2014	INV101-2014	\$880	Actions
20 January 2015	INV596-2015	\$1530	Actions
31 December 2014	INV352-2014	\$1880	Actions

Interaction history

Date	Type	Description
17 November 2014	📧	Re: Application for new medical device
18 November 2014	📞	Called sponsor agency to discuss the application sent for processing
20 November 2014	📧	Review application for requested data
22 November 2014	📧	Email comms were down and Fax was sent requesting information

Site design for submitters and drafters



Drafter / Submitter dashboard

In a Submitter / Drafter role, the view will show:

1. My work
2. Work in progress
3. In the Drafts tab you can see the drafts your organisation is currently working on

Applications Documents Your TGA

Welcome Mary Jones

What would you like to do today?

Pharma Co Pty Ltd (64013)

ABN:
ACN:
Web: <http://www.example.com>

View my organisation

News panel View more news

Clients Please Note 11/12/2014
The TGA has successfully transitioned from Westpac Banking Corporation (Westpac) to the Commonwealth Bank of Australia (CBA) for all transactional ban...

Update to medical device incident report notification processes 27/11/2014
As of 1 December 2014 the process for notifying sponsors of the completion of device incident reports (DIR) will be changing. For all reports received...

Australian manufacturers of medical 05/11/2014

1 My work
Work on drafts
View submissions

2 Work in progress View all drafts

3 Drafts Submissions

Date	Identifier	Client reference	Information	Sponsor
02 April 2015	OM-2015-GL-00002-1	None	New OTC	Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00267-3	640113-A	New Manufacturer A	Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00268-3	640113-B	New Manufacturer B	Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00269-3	640113-C	New Manufacturer C	Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00270-3	640113-D	New Manufacturer D	Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00271-3	640113-E	New Manufacturer E	Pharma Co Pty Ltd

Interaction history

Date	Type	Description
02 April 2015	☎	Phone Call

Submissions

In the Submissions tab you can see your organisation's latest submissions.

Welcome Mary Jones

What would you like to do today?

Pharma Co Pty Ltd (64013)



ABN:
ACN:
Web: <http://www.example.com>

[View my organisation](#)

My work

[Work on drafts](#)
[View submissions](#)

News panel

[View more news](#)

****Clients Please Note****

11/12/2014

The TGA has successfully transitioned from Westpac Banking Corporation (Westpac) to the Commonwealth Bank of Australia (CBA) for all transactional ban...

Update to medical device incident report notification processes

27/11/2014

As of 1 December 2014 the process for notifying sponsors of the completion of device incident reports (DIR) will be changing. For all reports received...

[Australian manufacturers of medical...](#) 05/11/2014

Work in progress

[View all submissions](#)

[Drafts](#)

[Submissions](#)

Received	Identifier	Workflow status	Description	Product name	Sponsor
02 April 2015	DV-2014-MC-00261-3	Under Review	640113-F		Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00263-3	Under Review	640113-H		Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00264-3	Under Review	640113-I		Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00265-3	Under Review	640113-J		Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00262-3	Under Review	640113-G		Pharma Co Pty Ltd

Interaction history

Date	Type	Description
02 April 2015	☎	Phone Call

Applications

This menu gives you access to TGA applications

The screenshot shows the TGA Applications menu. The 'Applications' menu item is circled in red. The menu is organized into columns with the following categories and items:

- Biologicals**
 - Biological Application Submission
- Medicine Shortages**
 - Notification Submission
- Prescription Medicine**
 - Pre-Submission
 - Single Medicine Application
 - Composite Pack Application
 - Submission
- Listed Medicine**
 - General Listing
 - Composite Pack
 - Code Stock
 - Medicine Kit
 - Change Multiple Current Listings
 - Submission
 - Listed Medicine Label
 - Checklist
 - Welcome Page
- Regulatory Actions**
 - Sponsor Cancellation
- Export Only Medicine**
 - S.26a - Solely for Export
 - S.26 - Export Only
 - General Listing
 - Composite Pack
 - Change Multiple Current Listings
 - Export Certificates
 - Listable Product (CLP)
 - Pharmaceutical Product (CPP)
 - Exempt Product (CEP)
 - Submission
 - Export Only
 - Solely for Export
 - Certificates
- Manufacturers**
 - Certification Application
 - Clearance Application
 - Declaration
 - Licence Application
- Over The Counter Medicine**
 - News: System Upgrade in Progress
 - Non-Prescription Medicine
 - Non-Prescription Composite Pack
 - Change Multiple ARTG
 - Entries
 - Welcome Page
 - Substance
 - Substance Application
 - Submission
- Medical Device**
 - Device/OTG Application
 - Joint Implant
 - Reclassification
 - Class III/AIMD Variation
 - IVD In-house Notification
 - Manufacturer Evidence
 - Conformity Assessment
 - IVD Variation
 - Request Change
 - GMDN Help
 - Medical Device Incident Reporting

At the bottom of the menu, there is a purple bar with 'Work in progress' and a 'View all drafts' button. Below this bar are two tabs: 'Drafts' and 'Submissions'.

Documents

This menu allows you to upload documents to applications, including:

- Clearances, licences or certifications for a medicine manufacturer
- Consumer Medicine Information
- Product Information

The screenshot shows the TGA portal interface. At the top, there is a navigation bar with 'Applications', 'Documents', and 'You: TGA'. The 'Documents' menu is highlighted with a red circle, showing options for 'Manufacturers', 'Consumer Medicine Information', and 'Product Information'. Below the navigation bar, there is a 'Welcome' message and a 'What would you like to do today?' section. The 'Pharma Co Pty Ltd (64013)' profile card is visible, showing a grid icon and a 'Web: http://www.example.com' link. Below this, there is a 'View my organisation' link. The 'My work' section contains 'Work on drafts' and 'View submissions' links. The 'News panel' features two news items: '**Clients Please Note**' dated 11/12/2014 and 'Australian manufacturers of medical devices - third party certification.' dated 05/11/2014. The 'Work in progress' section includes a 'View all drafts' link and a table of drafts.

Date	Identifier	Client reference	Information	Sponsor
02 April 2015	OM-2015-GL-00002-1	None	New OTC	Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00267-3	640113-A	New Manufacturer A	Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00268-3	640113-B	New Manufacturer B	Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00269-3	640113-C	New Manufacturer C	Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00270-3	640113-D	New Manufacturer D	Pharma Co Pty Ltd
02 April 2015	DV-2014-MC-00271-3	640113-E	New Manufacturer E	Pharma Co Pty Ltd

Your TGA

This menu shows your:

- Current ARTG Entries
- Consumer Medicine and Product Information
- In-house IVD's
- Manufacturer information
- Medical Device Evidence
- Medicines Shortage

The screenshot shows the TGA user interface. At the top, there are navigation tabs for 'Applications', 'Documents', and 'Your TGA'. The 'Your TGA' dropdown menu is open, showing a list of options: 'Current ARTG Entries', 'Consumer Medicine and Product Information', 'In-house IVDs', 'Manufacturer information', 'Medical Device Evidence', and 'Medicines Shortage'. A red circle highlights this menu. Below the menu, the user is logged in as 'Lisa Williams'. The main content area is divided into sections: 'Pharma Co Pty Ltd (64013)' with details like ABN, ACN, and Web; 'My work' with 'Work on drafts' and 'View submissions'; and 'Work in progress' with 'View all drafts'. A table at the bottom shows draft submissions with columns for Date, Identifier, Client reference, Information, and Sponsor.

Date	Identifier	Client reference	Information	Sponsor
02 April 2015	OM-2015-GL-00002-1	None	New OTC	Pharma Co Pty Ltd

View my details

1. This screen can be accessed by clicking on Account settings

It allows you to:

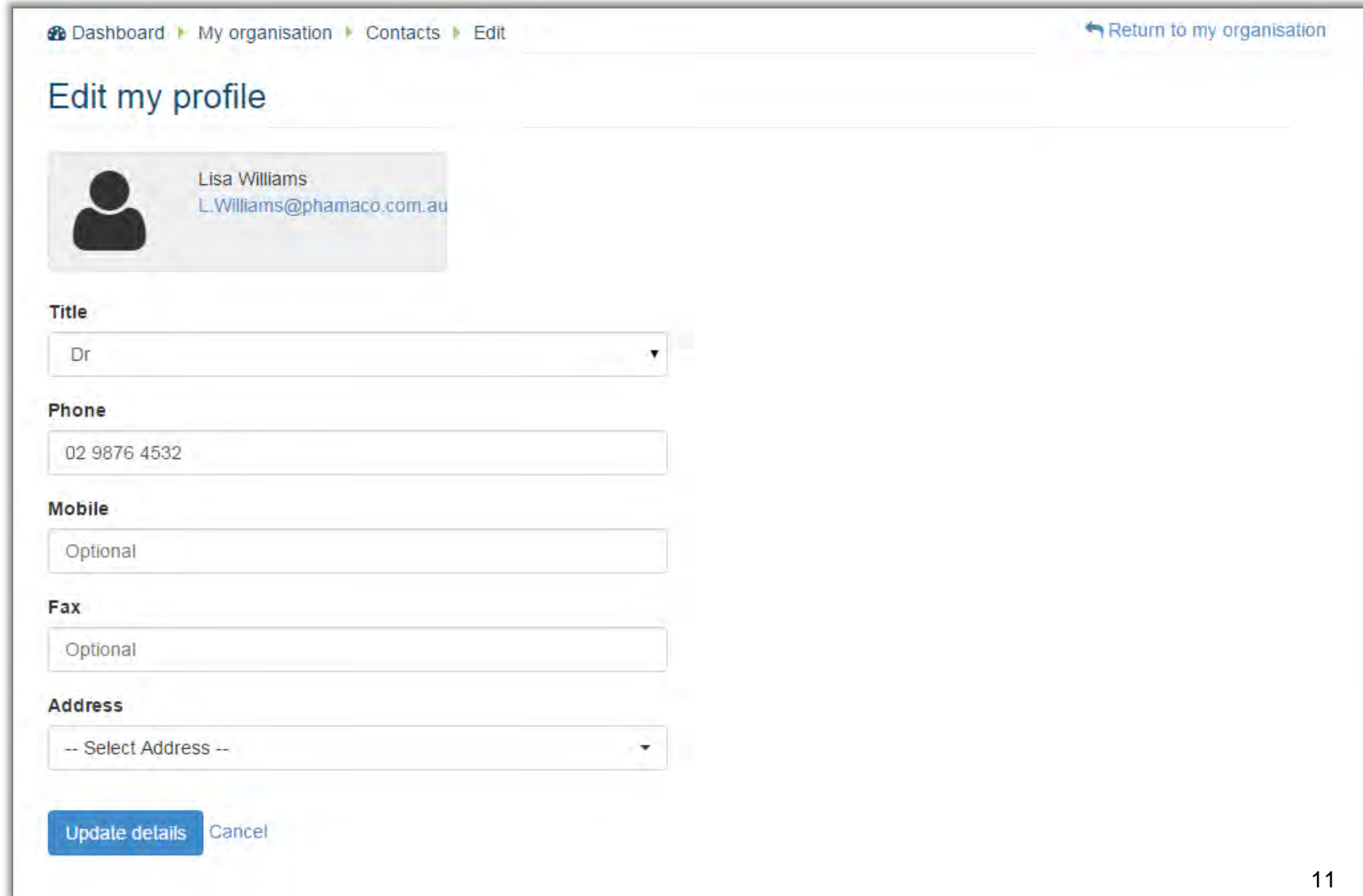
2. View your details
3. Edit your profile and change your password

The screenshot displays the 'View my details' page. At the top right, a user menu (1) is circled in red, containing 'Account settings', 'Change my password', and 'Sign out'. The breadcrumb navigation shows 'Dashboard > My organisation > Contacts > View', with 'View my details' (2) circled in red. The main content area shows a user profile for Dr Lisa Williams (126240_64013) with contact information. Below the profile, there is a section for 'System roles' listing 'Submitter'. To the right, an 'Administrative actions' (3) section is circled in red, containing 'Edit my profile' and 'Change my password'.

Edit my profile

This screen allows you to update:

- Title
- Phone
- Mobile
- Fax
- Address



The screenshot shows a web interface for editing a user profile. At the top, there is a breadcrumb trail: [Dashboard](#) > [My organisation](#) > [Contacts](#) > [Edit](#). A [Return to my organisation](#) link is in the top right. The main heading is "Edit my profile". Below this is a profile card for "Lisa Williams" with the email "L.Williams@phamaco.com.au". The form contains several fields: "Title" (a dropdown menu with "Dr" selected), "Phone" (a text input with "02 9876 4532"), "Mobile" (a text input with "Optional"), "Fax" (a text input with "Optional"), and "Address" (a dropdown menu with "-- Select Address --"). At the bottom, there are two buttons: "Update details" (highlighted in blue) and "Cancel".

The future

This is the first upgrade to the system
- more improvements are planned.

