

**From:** Smith, Charles  
**Sent:** 10/03/2011 11:59:37 AM  
**To:** Dean King; Villarreal, Carolina  
**Subject:** RE: Run of new Marlex BSC has secured from China

**Importance:** High

Dean

Just met with Carolina, a few questions to complete this. We can talk about/confirm tomorrow AM in our meeting.

I have alerted people to the PO coming together tomorrow to initiate process to allow for extrusion on next Monday to start.

1. Cost for extrusion, does that cover the data form Luxilon to be sent to BSC. Assume this is normal run data and no additional charges.

2. Cost of testing (phase # 4); does it take this much time to complete these typical production tests? How are they normally built into production run costs? Does this mean that the weaving costs will be less for the rest of the fiber, if we give the ok?

Charlie

-----Original Message-----

From: Dean King [mailto:Dean.King@proxybiomedical.com]  
Sent: Monday, October 03, 2011 12:01 PM  
To: Smith, Charles  
Subject: RE: Run of new Marlex BSC has secured from China  
Importance: High

Hi Charlie,

Please find attached Marlex (New Batch) qualification at Proxy Biomedical for your review. This proposal is based on the BSC test protocol (attached also).

Can you please confirm go ahead for this proposal as I need to issue a PO for the fiber extrusion at luxilon upon receipt of BSC approval?

Please feel free to call me if you have any concerns or questions.

Thanks in advance,  
Dean

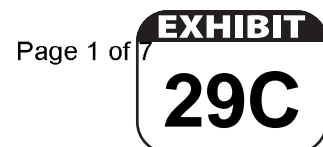
-----Original Message-----

From: Dean King  
Sent: 30 September 2011 21:31  
To: Smith, Charles  
Subject: RE: Run of new Marlex BSC has secured from China

We will provide a full project quotation including the extrusion on Tuesday.

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From: Smith, Charles [Charlie.Smith@bsci.com]  
Sent: 30 September 2011 21:21



To: Dean King  
Subject: RE: Run of new Marlex BSC has secured from China

The more, the better

Sent from my Verizon Wireless Phone

-----Original Message-----

From: Dean King <Dean.King@proxybiomedical.com>  
Sent: Friday, September 30, 2011 4:18 PM  
To: Smith, Charles <Charlie.Smith@bsci.com>  
Subject: RE: Run of new Marlex BSC has secured from China

Hi Charlie,

Do you want the fibre extrusion price only or the full qualification price?

We will be working on the proposal for Monday.

Dean

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From: Smith, Charles [Charlie.Smith@bsci.com]  
Sent: 30 September 2011 19:22  
To: Dean King  
Subject: RE: Run of new Marlex BSC has secured from China

Forgot to ask about \$\$ on this?? Need PO in for next week to allow run on OCT 10 at Luxilon.

From: Smith, Charles  
Sent: Monday, September 26, 2011 7:49 AM  
To: 'Dean King'; Nico Van Malderen  
Cc: Thierry Beyltiens; Peter Mulrooney  
Subject: RE: Run of new Marlex BSC has secured from China

Just pinnacle, plan is to use normal manufacturing settings and conditions as we do for production currently.

From: Dean King  
[mailto:Dean.King@proxybiomedical.com]<mailto:[mailto:Dean.King@proxybiomedical.com]>  
Sent: Monday, September 26, 2011 7:47 AM  
To: Smith, Charles; Nico Van Malderen  
Cc: Thierry Beyltiens; Peter Mulrooney  
Subject: RE: Run of new Marlex BSC has secured from China

Just so I am clear?

Will we be using the proxy biomedical PPS numbers for the extrusion of these fibers?

PPS50023 - 4mil Blue  
PPS50031 - 4 mil Natural

Charlie,

Can you also confirm that we will be extruding sufficient fibers to manufacture both Pinnacle& Pinnacle Lite?

Nico/Thierry,

I will confirm the correct quantity (kg), number of ends & spools required for this extrusion run following our meeting with BSC.

Dean

[cid:image001.jpg@01CC7F7C.686E67C0]

Dean King | Senior Project Engineer | Proxy Biomedical Limited.

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From: Smith, Charles [mailto:Charlie.Smith@bsci.com]<mailto:[mailto:Charlie.Smith@bsci.com]>

Sent: 26 September 2011 12:11

To: Nico Van Malderen; Dean King

Cc: Thierry Beyltiens

Subject: RE: Run of new Marlex BSC has secured from China

That is ok. We can work out the amount, I do not want to miss the window to run you provided.

From: Nico Van Malderen

[mailto:nico.vanmalderen@luxilon.be]<mailto:[mailto:nico.vanmalderen@luxilon.be]>

Sent: Monday, September 26, 2011 3:51 AM

To: Smith, Charles

Cc: Thierry Beyltiens

Subject: FW: Run of new Marlex BSC has secured from China

Importance: High

Charlie,

I understand we have to quote then for PP marlex 25 kilos natural 1 batch and 1 kilo blue 1 batch, all to be produced together one after the other.

All metered spools and non-full spools added.

I am travelling so not sure when I get you reply, if I can send you quotation right away, but last time I will do it is Thursday morning our time. Is that okay?

Regards

NICO

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P Consider the environment - do you really need to print this email?

Van: Thierry Beyltiens  
Verzonden: maandag 26 september 2011 7:56  
Aan: Nico Van Malderen  
Onderwerp: FW: Run of new Marlex BSC has secured from China  
Urgentie: Hoog

Thierry Beyltiens,  
Regulatory Affairs Manager  
Luxilon Industries NV

Van: Smith, Charles [mailto:Charlie.Smith@bsci.com]<mailto:[mailto:Charlie.Smith@bsci.com]>  
Verzonden: vrijdag 23 september 2011 22:58  
Aan: Dean King (Dean.King@proxybiomedical.com<mailto:Dean.King@proxybiomedical.com>); 'Dave Ruder'; Thierry Beyltiens  
CC: Cuddy, Christopher; Courtois, Janice; Villarreal, Carolina; Podmore, Adrienne; Raneri, Joe  
Onderwerp: RE: Run of new Marlex BSC has secured from China  
Urgentie: Hoog

Dean

Need the quote for the run. Work with Luxilon. They had window to run the week of OCT 10. I want to get POs going end of next week. I will coordinate the shipment of material with Chris Cuddy to Luxilon.

Pinnacle: both clear and blue.

-Cost to extrude both fibers. Gather the run data on OD, tensile, etc. using current settings.  
-Cost to weave mesh. Gather the run data using current settings. Place into hold after run.

Dave

Need quote for your part as well, we can discuss on Monday meeting.

-Cost for tack weld from MedVenture. Current settings. Any unused units will be placed in hold after tests are run.

We will generate a protocol next week to layout this processing through system ( in production quarantined for not for human use status). We will then generate a report to review the units run which could eventually allow for the material to be released for production use and take off of hold.

DRAFT Timing:

TASK	TIMEING	RESPONSIBLE PERSON
Protocol Quotes	DRAFT 9/28 9/28, 9/30	Carolina/Janice Dean, Dave

POs	10/3, 10/10	Charlie, Charlie
Ship resin	9/30	Chris/Charlie
Run extrusion	10/10- 10-21	Luxilon
Weave	11/14	Proxy
Form shapes	11/28	Proxy
Tack weld/assembly	12/12	MedVenture
Draft Report	12/28	Carolina/Janice

thks

Charlie  
From: Smith, Charles  
Sent: Tuesday, September 13, 2011 2:40 PM  
To: 'Dean King'  
Subject: RE: Run of new Marlex BSC has secured from China  
Importance: High

Dean

The family will be Pinnacle as this is our high runner and tack weld is more challenging post process at MedVenture for final assembly.

Charlie

From: Smith, Charles  
Sent: Tuesday, September 13, 2011 10:16 AM  
To: 'Dean King'  
Subject: RE: Run of new Marlex BSC has secured from China

Ok, thks

From: Dean King  
[mailto:Dean.King@proxybiomedical.com]<mailto:[mailto:Dean.King@proxybiomedical.com]>  
Sent: Tuesday, September 13, 2011 10:08 AM  
To: Smith, Charles  
Subject: RE: Run of new Marlex BSC has secured from China

Thank you Charlie,

Once you confirm Product Family (Pinnacle Lite) I will put a proposal together.

At a high level and based on the Luxilon extrusion dates we should be in a position to carry this work out in early November. I will confirm at time of proposal.

Regards,  
Dean

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From: Smith, Charles [Charlie.Smith@bsci.com]  
Sent: 13 September 2011 15:02  
To: Dean King  
Subject: RE: Run of new Marlex BSC has secured from China See in blue below.

From: Dean King  
[mailto:Dean.King@proxybiomedical.com]<mailto:[mailto:Dean.King@proxybiomedical.com]>  
Sent: Tuesday, September 13, 2011 9:54 AM

To: Smith, Charles  
Subject: RE: Run of new Marlex BSC has secured from China

Hi Charlie,

Can you please confirm the product family to be knit? Pinnacle LITE? Will confirm, I assume this will be worst case for bio and processing.

Will we be required to perform an extrusion validation at luxilon or will we extrude a single lot based on our current validated Marlex fibre extrusion parameters? No, run to validated setting to prove no issues.

Likewise here at Proxy Biomedical, what level of validation will be required? PQ & PPQ? Run to current setting, no changes.

When do you expect your initial resin test results? In next few days some tests will start and results will be forthcoming.

Please feel free to call me or schedule a conference call to discuss further if necessary.

Regards,  
Dean

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From: Smith, Charles [Charlie.Smith@bsci.com]  
Sent: 13 September 2011 14:20  
To: Dean King; Thierry Beyltiens  
Cc: Peter Mulrooney  
Subject: Run of new Marlex BSC has secured from China Dean/Thierry

Assuming we have good test results for the resin we secured from China, next potential step could be to run some ASAP in production mode. This expedited step is being raised as we have only worked off of one lot since we have been validated with both of you over the past three years.

Could you provide a quote to me for the following:

1. Cost to extrude
2. Cost to weave.
3. Cost to form as needed post weaving @ Proxy.

I assume we will run the pinnacle lite blue as is worst case, I will have this determined in next few days.

How much resin I should have shipped you to allow for runs.  
Soonest we could start extrusions runs?  
Soonest we could start weaving runs?

Thks

Charlie

