

## Delphi Consulting Group (DCG)

11874 South Evelyn Circle  
Houston, Texas 77071-3404  
harvey.knauss@gmail.com  
Tel 832-675-9281  
Fax 713-723-0786  
[www.delphiconsulting.com](http://www.delphiconsulting.com)

DCG is a boutique US FDA regulatory assistance firm serving worldwide medical device manufactures with product release in the US and Canadian market. With the following services; Good Manufacturing Practices [GMPs], documentation, acting as US Agent, and other FDA and Health Canada interface requirements. Our small size and low overhead costs allow us to provide prompt response to needs, with equitable overall costs. DCG's client base is worldwide. DCG works to make all tasks and task costs as transparent as possible.

### Consulting Terms and Fees

Consulting services from Delphi Consulting Group (DCG) are provided to clients under the following conditions and terms:

- DCG personnel act as an independent consultant and not as an agent or employee of client i.e. IRS 1099. DCG shall be responsible for all taxes as an independent consultant.
- DCG shall have no authority to bind client or incur obligations on behalf of client except when specified in a signed and dated contract agreement.
- A signed, dated agreement of confidentiality and consulting agreement between client and DCG shall precede any services.
- All produced document are provided without copyright in Word (doc or docx), Word-Perfect X7, and/or TextMaker file formats in Windows or Linux OS as selected by client. All files stored in Dropbox folders with 'Share.' All supplied Federal Government data/documents provided "as is."

### Detailed Breakdown of DCG Fee Structure

Fees determined by quotation, fixed price, or person-day basis. Each client's regulatory needs are unique and thus require a complete review for an acceptable proper Consulting Agreement and Statement of Work (SoW) and Cost Quotation.

Task Description	Hourly Billing Rate	Comments
General Regulatory/Submissions	\$85.00 US	All general regulatory tasks. Used as a billing rate for Not to Exceed Cost Quotations. Time billed in fifteen minute increments.
E-mails requesting information and require re-search	\$85.00 US	Billing maybe accumulated for the month or billed as running time.

Task Description	Hourly Billing Rate	Comments
Teleconferences when DCG is the host	\$85.00 US	Billed as true running time in one minute increments. DCG utilizes Skype, Zoom, or Talky for host.
Teleconferences as participant only	\$45.00 US	Billed as true running time in one minute increments.
<b>Not to Exceed</b> Cost Quotations	As quoted	Applies only to submissions with established FDA process does not consider extra tasks.
Client Retainer Contracts	As quoted	This style of contract can be advantageous for clients with defined needs on going.

42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65  
66  
67  
68  
69  
70  
71  
72  
73  
74  
75  
76  
77  
78  
79  
80  
81  
82  
83

The above rates include normal office supplies and computer services. All non-labor services billed without mark up. Time billed in quarter-hour increments. Document Copies, binders, FedEx, and other expenses required when submission are sent to the FDA are billed at cost.

**Estimated costs of common tasks**

**The following provided for budget estimates only.** Each task requires an analysis to determine true DCG costs or estimated costs. Fixed price, turnkey contract(s) possible for common devices. All estimates shown are based on **no** travel. DCG utilizes the Internet to reduce travel to zero. After 30 years of submission experience DCG does not believe any travel is required to provide successful FDA release to market for any device. This is a real cost saving to client.

**Costs - Typical - Safety Testing and Submission**

The following provided for **budget estimates only**. Each task requires an analysis to determine true testing costs or estimated costs. Fixed price contract possible for common devices from some testing companies.

**Safety Testing [General]**

DCG Does not conduct any testing.  
Estimated costs are for Certified Testing Companies.

- Safety Testing electro/mechanical device – ranges between \$ 8,500 to \$ 20,000
- EMI Testing – range between \$ 7,000 and \$ 15,000
- Bio and Toxic – range between \$ 8,000 to >\$ 25,000
- Sterilization Validation – range between \$ 4,000 to >\$ 9,000
- Bench Testing – range between \$ 3,000 to A/R, very device dependent

**DCG Estimated Submission Preparation and Monitoring of FDA Review Fees**

- Traditional 510(k) submissions, less testing, FDA and/or 3 party review and validation costs.
- Non-powered disposable device..... \$ 5,000 to >\$ 10,500
- Non-powered disposable device – sterilized. .... \$ 6,000 to >\$ 12,500
- Non-powered implanted ..... \$ 7,000 to \$ A/R
- Powered, non-wireless, w/o sterilization needs. .... \$ 6,000 to >\$ 12,500
- Powered, wireless with/without sterilization needs. .... \$ 6,500 to >\$ 15,500

84  
85  
86  
87  
88  
89

### FDA User Fees for F/Y 2019

The Fees for Fiscal Year 2019 (October 1, 2018 through September 30, 2019) are as follows:

Application Type	Standard Fee	Small Business Fees $\pm$
510(k) $\pm\pm$	\$10,953	\$2,738
513(g)	\$4,349	\$2,175
De Novo Classification	\$96,644	\$24,161
PMA, PDP, PMR, BLA	\$322,147	\$89,537
Panel-track supplement	\$241,610	\$60,403
180-day supplement	\$48,322	\$12,081
Real-time supplement	\$22,550	\$5,638
BLA efficacy supplement	\$322,147	\$80,537
Annual Report	\$11,275	\$2,819
30-day notice	\$5,154	\$2,577

90  
91  
92  
93  
94  
95  
96  
97  
98  
99  
100  
101  
102  
103  
104  
105  
106  
107  
108  
109  
110  
111  
112  
113  
114  
115  
116  
117  
118

$\pm$  For small businesses with an approved SBD.

$\pm\pm$  Note: all types of 510(k)s (Traditional, Abbreviated, and Special) are subject to the use fee. However, 510(k)s submitted to the FDA on behalf of an FDA-accredited third-party reviewer do not have a user fee. However, Third Party has a fee, often much higher than the FDA fee. Note: DCG's observation has not found any real advantage with the use of Third Party review and/or time saved.

Area in light blue is PMA submissions.

Small businesses with an approved SBD with gross receipts of sales of \$ 30 Million or less are eligible to have the fee waived on their first PMA, PDP, PMR, or BLA. Note: SBD applications require release of company and/or investors tax information.

Annual Establishment Registration fee is \$4,884. A true physical address must be provided. There are no waivers or reductions for small establishments, businesses, or groups – all establishments must pay the same establishment registration fee.

Web page for filing for Small Business Certification: <https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm615142.htm>

Small Business Certification is free and requires an annual renew.

Note: All **User Fees** must be paid in full one or two days > before a submission is sent in to the FDA.

119  
120  
121  
122  
123  
124  
125  
126  
127  
128  
129  
130  
131  
132  
133  
134  
135  
136

## Disclaimer

DCG and contracted firms will make a good-faith effort to meet all current and established regulations, laws, and guidelines for the production of supplied documentation and counsel. However, the interpretation of regulations often is subject to individual understanding, thus, DCG cannot guarantee that another agency or person will reach the same conclusions in each case.

All submissions, reports and letters issued by Delphi Consulting Group are for the exclusive use of the client/sponsor to whom they addressed. Documents may not be reproduced except in their entirety. No quotation from reports or use of the company's name is permitted except as expressly authorized by Delphi Consulting Group or the document's client owner in writing. Delphi Consulting Group or the document's client owner makes no warranties if any kind, express or implied. Delphi Consulting Group or the document's client owner expressly states that the use of this data is the sole responsibility of the user. Delphi Consulting Group or the document's client owner shall not be liable for any incidental or consequential damages resulting from the application or use of this data.

Each DCG contract shall contain a client cancellation cost. This cancellation cost shall be based on the complexity and percent of completion of the task.

DCG Storage: C:\Users\Delphi Consulting\Dropbox\Dropbox from C:\DCG Files\DCG handouts\Billing rates Oct 2018.doc - TextMaker

<b>Delphi Consulting Group</b> (DCG) 832-675-9281 V 713-723-0786 F www.delphiconsulting.com harvey.knauss@gmail.com	<b>SUBJECT:</b> Budget Costs for FDA Submissions	Page 4 of 4  December 30, 2018 Rev B
---	--	---